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Regulatory Analysis: Proposed Premanufacture Notification and Review Procedures. Proposed Rule, Section 5, Toxic Substances Control Act

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Regulatory Analysis: Premanufacture Notification and Review Procedures

Proposed Rule, Section 5
Toxic Substances Control Act

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Section 5 of the Toxic Substances Control Act (TSCA) requires manufacturers and importers to notify EPA 90 days before they manufacture or import a new chemical substance. New substances are those that are not on the TSCA Chemical Substance Inventory, which was first published on June 1, 1979, and supplemented on July 30, 1980, by a Revised Inventory. EPA proposed regulations to implement section 5 requirements and to establish premanufacture notice and review procedures in the Federal Register of January 10, 1979 (44 FR 2242), October 16, 1979 (44 FR 59764), and August 15, 1980 (45 FR 54642). In this draft Regulatory Analysis, EPA explains the rationale for its proposal. The Regulatory Analysis also discusses the major issues raised by the proposed rules and describes the different alternatives the Agency considered for resolving the issues. The analysis is in part based on the proposed "Economic Impact Analysis of Proposed Section 5 Notice Requirements," prepared by ICF Incorporated of Washington, D.C.

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REGULATORY ANALYSIS
PROPOSED PREMANUFACTURE NOTIFICATION AND REVIEW PROCEDURES

TOXIC SUBSTANCES CONTROL ACT
SECTION 5

OCTOBER 1980

CHEMICAL CONTROL DIVISION
OFFICE OF TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

PREFACE

Executive Order 12044, "Improving Government Regulations," directs each executive agency to adopt procedures to improve existing and future regulations. An important provision of this order is that agencies consider and analyze meaningful alternatives before regulations are issued. For all significant regulations with major economic consequences, agencies must conduct a regulatory analysis, in which they carefully examine alternative approaches. The U.S. Environmental Protection Agency (EPA) described its plan for implementing the Executive Order, and listed criteria for conducting regulatory analyses, in the FEDERAL REGISTER of May 29, 1979 (44 FR 30988).

In this document, EPA presents a draft Regulatory Analysis of proposed rules implementing section 5 of the Toxic Substances Control Act (TSCA). Section 5 of TSCA requires manufacturers and importers to notify EPA 90 days before they manufacture or import a new chemical substance for commercial purposes. Section 5 also requires persons to notify EPA 90 days before they manufacture, import, or process a chemical substance for a significant new use, as determined by rule. EPA proposed regulations to implement section 5 requirements, and to establish premanufacture notice and review procedures, in the FEDERAL REGISTER of January 10, 1979 (44 FR 2242), October 16, 1979 (44 FR 59764), and August 15, 1980 (45 FR 54642). These rules will have an impact on major segments of the chemical industry, and they will affect the introduction of new chemical substances into commerce. Therefore, EPA has determined that the rules meet the criteria of its own guidelines and of Executive Order 12044 for a regulatory analysis.

The draft Regulatory Analysis examines the major alternatives that EPA considered in developing section 5 rules and explains the rationale for EPA's choice among the alternatives. EPA has based the analysis in part on the work of two contractors, Arthur D. Little, Inc. (ADL) and ICF Incorporated (ICF), which prepared economic impact analyses of major parts of the proposed rules. The studies by Arthur D. Little, "Impact of TSCA Proposed Premanufacturing Notification Requirements" (December 1978) and "Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form" (September 1979) have already been published and are available from the Industry Assistance Office of the EPA Office of Toxic Substances. EPA published a summary of ICF's proposed methodology in the FEDERAL REGISTER of June 10, 1980 (45 FR

39450), and it is now publishing the ICF report, "Economic Impact Analysis of Proposed Section 5 Notice Requirements," together with the draft Regulatory Analysis. The proposed Economic Impact Analysis and additional copies of this draft Regulatory Analysis are available from the Industry Assistance Office.

EPA encourages interested members of the public to submit written comments on the draft Regulatory Analysis and the proposed Economic Impact Analysis. EPA will consider these comments when preparing the final versions of these documents and the final section 5 rules. The final analyses will be published when the section 5 rules are promulgated early in 1981. Comments should bear the identifying notation OPTS-50018 and be addressed to: Document Control Officer (TS-793), Office of Toxic Substances, Room E-477, Environmental Protection Agency, 401 M Street SW, Washington, DC 20460. For further information, contact:

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I. INTRODUCTION

A. Purpose of TSCA

The Toxic Substances Control Act of 1976 gives the Environmental Protection Agency broad authority to regulate the manufacture, processing, distribution in commerce, use, and disposal of chemical substances. In doing so, it fills a major gap in U.S. environmental and toxic-chemical regulation. Previous laws limited Federal regulation of hazardous substances to particular uses (for example, as drugs, pesticides, or consumer products) or to particular conditions of exposure (for example, exposure to hazardous substances in the workplace or to air and water pollutants). TSCA, however, makes possible the regulation of toxic substances in all phases of their commercial life cycle. It gives EPA the authority to regulate certain hazards not readily controlled by other laws, and it enables EPA to control hazardous substances early in their life cycle.

In TSCA, Congress took a preventive approach to the regulation of chemical substances. A major focus of the Act is to prevent harm to health and the environment, rather than to address hazardous situations only after the damage has been done. This approach not only protects humans and the environment more effectively than an approach directed only at existing hazards, but it allows for more efficient and economical regulation. If hazardous substances are controlled early in commercial development, or before they enter commerce, the direct cost to the regulated industry, to labor, and to the economy in general will be low. This preventive approach is embodied in particular in section 5 of the Act, which gives EPA the authority to review risks associated with new chemical substances before they enter commerce and risks associated with new uses of existing chemical substances that the Agency has determined to be "significant new uses."

B. Scope of Section 5

Section 5 of TSCA requires chemical manufacturers and importers to notify EPA at least 90 days before manufacturing or importing a new chemical substance for a commercial purpose. New chemical substances are those that are not on the TSCA Chemical Substance Inventory, first published on June 1, 1979, as the Initial Inventory, and supplemented on July 30, 1980, by a Revised Inventory. In addition, under regulations proposed on August 15, 1980 (45 FR 54642), persons would be required under section 5 to notify EPA if they intended for the first time to process substances for TSCA commercial purposes that were manufactured or imported for purposes exempt from TSCA reporting.

Once EPA receives a section 5 notice, the Agency has 90 days to review it, unless for good cause it extends the review period under section 5(c) for up to an additional 90 days. During the review period, EPA may act under section 5(e) or 5(f) to regulate the production or use of the new chemical substance. Section 5(e) authorizes EPA to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance until the submitter provides sufficient information for an evaluation of its health and environmental effects. The Agency can take this action if it determines that the available information is insufficient for a reasoned evaluation and either (1) the substance may present an unreasonable risk of injury to health or the environment, or (2) the substance will be produced in substantial quantities and there may be significant or substantial exposure to the substance. Under section 5(f), EPA may regulate a new chemical substance if it finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the substance will present an unreasonable risk of injury to health or the environment.

If EPA or a Federal court has not banned manufacture, processing, or import of the chemical substance during the review period, these activites may begin, subject to limits or testing requirements imposed during the review period. At that time, the substance is added to the Inventory. Thereafter, any person may manufacture or import the substance without giving notice to the Agency.

Premanufacture notification requirements went into effect on July 1, 1979, 30 days after the publication of the Initial Inventory. An Interim Policy, published by EPA in the FEDERAL REGISTER of May 15, 1979 (44 FR 28558) governs the submission and review of notices until final rules are issued. EPA proposed rules and notice forms to implement a premanufacture notification and review program in the FEDERAL REGISTER of January 10, 1979 (44 FR 2242), and reproposed the rules and forms in part in the FEDERAL REGISTER of October 16, 1979 (44 FR 59764). EPA has also proposed processor notification rules in the FEDERAL REGISTER of August 15, 1980 (45 FR 54642). These rules would require that persons notify EPA 90 days before they process substances which were previously exempt from TSCA reporting.

The draft Regulatory Analysis discusses the major issues that arose in developing these proposals, the alternative approaches to their resolution that EPA considered, and the rationale for EPA's choice among the alternatives. The proposed rules will be promulgated early in 1981. The final Regulatory Analysis will be published at the same time.

C. Section 5 Rulemaking

1. Possible Components of a Section 5 Rulemaking

In proposing these rules, EPA considered the possibility of a broad rulemaking fully implementing section 5. Such a rulemaking could include: (1) Clarification of the nature and scope of reporting obligations, (2) Instructions on what information must be submitted in section 5 notices, (3) An explanation of Agency procedures for reviewing and acting on notices, (4) Procedures for exempting certain chemical substances from all or part of section 5 requirements, and (5) Procedures for following up new chemical substances after they have entered commercial production. The rules proposed on January 10, 1979, October 16, 1979, and August 15, 1980, address the first three elements; the other two elements will be the subject of later rulemakings.

In addition, the premanufacture notification program could include guidance for premanufacture testing, discussed in the FEDERAL REGISTER notice "Discussion of Premanufacture Testing Policy and Technical Issues: Request for Comment," published on March 16, 1979 (44 FR 16239). This guidance would not provide mandatory requirements for premanufacture testing.

a. Clarification of reporting obligations. A section 5 rulemaking might clarify the nature and scope of the notice obligation, giving submitters a clear understanding of the extent of their responsibilities under section 5. Simply citing the language of the statue in many cases would not provide clear guidance. Under the Interim Policy of May 15, 1979, which generally uses this approach, EPA has often been required to answer industry questions on notice requirements and to clarify its interpretation of the Act. In a more extensive rulemaking, EPA could explain in detail its interpretation of the Act instead of responding to individual inquiries. In addition, the rules could explain the scope of reporting obligations. For example, they could specify who should submit a notice as an "importer," and they could define the extent to which submitters would be obligated to ask customers for information on processing, distribution in commerce, use, or disposal of new chemical substances. In this way, the rules would promote a consistent EPA approach and reduce uncertainty. This was the approach that EPA took in the January, October, and August proposals.

b. Information requirements. Section 5(d) of TSCA requires that notices include test data in the possession or control of the submitter, and, insofar as it is known to or reasonably ascertainable by the submitter, information on chemical identity; proposed categories of use; proposed volume of production; byproducts resulting from manufacture, processing, use, or disposal; workplace exposures; and manner or method of disposal. In a section 5 rulemaking, EPA could define information requirements by citing the relevant sections of the Act; it could provide a narrative explanation of these requirements and possibly require other information related to exposure throughout the life cycle of the substance; or it could provide a notice form to clarify and provide a standard format for the information described in the narrative explanation.

Under the Interim Policy, EPA has found that the first alternative does not provide adequate guidance to submitters, and in many cases this approach does not give the Agency enough information to evaluate possible risks associated with new chemical substances. In the second alternative, the Agency could clarify such terms as "test data" and "disposal," and it could specify the submission of other information necessary for an evaluation -- for example, information on exposure associated with consumer uses. The Agency could also develop notice forms to accompany the rule. These forms would allow clearer instructions on what information the submitter would have to include in the notice, and they would greatly facilitate EPA's review of notices within the short time allowed by the Act. EPA proposed such forms in the January and October rules.

c. Explanation of Agency procedures. The rules could describe the procedures by which the Agency would review, and possibly act on, notices. In this way, the rules would provide submitters with a clear idea of what they could expect, and they would eliminate some of the uncertainty surrounding the submission of a notice. The rules could establish policy and procedures for handling confidential information; for processing and reviewing notices, including a policy on incomplete submissions; for securing additional data from the submitter or other persons during the notice period; and for using the regulatory authorities of sections 5(e) and 5(f). Again, this is the approach that EPA has adopted in its proposed rules.

d. Exemption policy. The rule could establish a comprehensive exemption policy under section 5(h), including exemptions for test marketing, for research and development, and for substances determined not to present an unreasonable risk of injury to health or the environment. The January proposal discusses the research and development exemption under section 5(h)(3), which exempts persons who manufacture or process a new chemical substance solely for research and development "in small quantities." But it does not specifically define the terms of the exemption, including the meaning of "small quantities." The

Agency may in future rulemakings establish numerical or other more precise definitions of small quantities for specific substances or groups of substances.

The proposed rule also discusses test marketing exemptions, which are granted upon a showing that the test marketing of the substance will not present an unreasonable risk of injury to health or the environment. The proposed rule, however, does not fully define the requirements for a test marketing exemption, nor does it specify the procedures by which EPA will review test marketing exemption applications. Under the Interim Policy, EPA has found that the absence of a framework for test marketing exemptions can impose a burden on the submitter. In a future rulemaking, EPA may clarify the test marketing exemption and possibly develop a test marketing application form.

EPA also has the authority to develop an exemption policy under section 5(h)(4). This section allows the Agency, upon application and by rule, to exempt manufacturers or importers from all or part of the section 5 requirements if it determines that the manufacture, processing, distribution in commerce, use, and disposal of a new chemical substance will not present an unreasonable risk to health or the environment. In the future, EPA may propose procedures for exempting substances under this section.

e. New-chemical followup program. A section 5 rulemaking could establish a new-chemical followup program. Such a program would allow EPA to obtain information on selected new chemical substances after they have entered commercial production, and to reassess certain new chemical substances before they are produced for new uses that may significantly increase their risk to human health or the environment. EPA could establish the program under two TSCA authorities: the section 8(a) reporting authority and the section 5(a)(2) significant new use authority.

Although the proposed rules do not implement followup procedures, EPA will soon propose significant new use rules for specific new chemical substances. These proposed rules will require persons to notify EPA 90 days before they manufacture or process the substances subject to the rules for a significant new use, as defined by the rules. EPA is also developing a model significant new use rule and a model section 8(a) reporting rule that can be applied to specific new substances of concern. The Agency will publish an Advance Notice of Proposed Rulemaking for these model rules in the near future. The model rules will include notification and review procedures, information requirements, and definitions of possible significant new uses.

EPA will apply these model rules to specific new chemical substances in abbreviated rulemakings. The Agency may also apply the model significant new use rule to existing chemicals as an interim measure before it develops a general framework for using the significant new use authority for existing chemicals.

f. Testing guidelines. As discussed in the January proposal and the Discussion of Premanufacture Testing and Policy Issues of March 16, 1979, EPA could publish premanufacture testing guidance. Such guidance would recommend the types of data generally needed for premanufacture risk assessment and appropriate test methods for developing these data. EPA has decided to publish premanufacture testing guidance consistent with the premarket "base set" of data developed by the Organization for Economic Cooperation and Development (OECD). This testing guidance will be published in the FEDERAL REGISTER in the near future.

2. Components of Proposed Rulemaking

The section 5 rules proposed on January 10, 1979, October 16, 1979, and August 15, 1980, are limited in scope; they specify information requirements, provide notice forms, clarify the nature of the reporting obligation, and explain Agency procedures for reviewing and acting on notices. EPA has not proposed a comprehensive exemption policy, or a new-chemical followup program. These will be the subject of later rulemakings. This limited approach to section 5 rulemaking will ensure an effective premanufacture review program, without delaying the promulgation of rules until all issues surrounding possible section 5 rulemakings have been resolved.

The major provisions of the proposed approach are summarized below. EPA is considering alternatives to each of these provisions; the alternatives, and EPA's rationale for its preferred approach, are discussed in this draft Regulatory Analysis.

a. Reporting requirements. EPA prefers the approach of the October 16 reproposal. In this approach, submitters would be required to complete a limited form, asking for information on chemical identity, manufacturing process, occupational exposure, environmental release and disposal, and commercial user and consumer exposure. They would also submit all test data in their possession or control and a description of any other data known to or reasonably ascertainable by them. EPA would select substances of concern for detailed review on the basis of information in the notices. For the few substances subject to such a review, EPA could require additional data from the submitter or certain other persons under the supplemental reporting authority described below.

b. Confidentiality. There are four issues involving confidentiality: (1) How the submitter claims information confidential; (2) When he must substantiate his claims; (3) How EPA will handle confidential information in public notices; and (4) When EPA will disclose confidential chemical identity as data underlying a health and safety study.

In the preferred approach, submitters would assert claims of confidentiality by linking the information claimed confidential to certain categories of information established by EPA. The submitter would be required to substantiate all confidentiality claims at the time the notice was submitted. Confidential information would be masked by generic names or descriptions in section 5(d)(2) and other public notices. Confidential chemical identity that is underlying data to a health and safety study would not be disclosed until commencement of manufacture. The Agency, however, is also considering the possibility of protecting chemical identity for a set period after manufacturing begins.

c. Incomplete submissions. On January 10, EPA proposed an approach to incomplete submissions that divided deficiencies into major and minor categories. If the deficiency was major (for example, failure to supply known or reasonably ascertainable information required by the form), EPA would not review the submission, and the notice period would not start. If the deficiency was minor (for example, typographical errors that make answers to any questions unclear or ambiguous), the notice period would be suspended until the deficiency was corrected. If the submitter corrected the deficiency within 30 days, EPA would start the review clock at the point where it stopped. If the deficiency was not corrected, EPA could return the notice as incomplete and stop the review. EPA is also considering a narrower set of criteria for determining that a notice does not meet the requirements of the Act. Under this alternative, EPA would not stop the review period if it found minor deficiencies in a notice. The January 10 proposal did not include appeal procedures for submitters; the Agency, however, is considering such procedures for the final rule.

d. Customer contact. Frequently, customers will have information on the processing, uses, and disposal of new chemical substances that is not known to the notice submitter. This information might be necessary for EPA's evaluation. To secure the information, EPA prefers an alternative approach discussed in the Preamble to the October 16, 1979, reproposal. As described in the Preamble, this approach would require the submitter to indicate in the notice the number of customers who had made a firm commitment to purchase the substance for a use unknown to him. The submitter would also be required to estimate the percentage of production volume that these customers would purchase in the first three years of manufacture.

e. Definition of importer. Importers as well as manufacturers are subject to the notice requirements of section 5. EPA prefers a broad definition of importer, proposed on January 10, 1979, which includes all possible parties in an import transaction. On September 23, 1980, EPA published a clarification of this definition, which would require that the "principal importer" submit the notice (45 FR 63806).

f. Importer contact of foreign manufacturers/suppliers EPA proposes that importers be required to contact foreign manufacturers and suppliers, who would be asked to submit a Foreign Manufacturers/Suppliers Form. This approach was originally proposed on January 10. EPA is now considering an abbreviated form, which might be modeled on the October 16 form, or which might be still further reduced so that it asks only for health and safety data and risk assessments.

g. Exporters. On January 10 and October 16, EPA proposed that manufacturers of chemicals solely for export be required to submit a section 5 notice. The notices would not include information on uses and exposure occurring outside of the United States.

h. Supplemental reporting. In certain cases, EPA may require additional information from the submitter, from potential processors, or from other persons during the review period in order to complete its evaluation. EPA prefers the approach to supplemental reporting of the October 16 reproposal. In this approach, the Agency could require, under a section 8(a) or 8(d) letter-writing authority, that certain persons during the review period provide specified types of information necessary for assessing the potential risk of a new chemical substance. The submitter of the notice, processors, manufacturers or importers of reactants of unknown composition, and persons who have relevant health and safety studies could be subject to supplemental reporting under this authority. Persons could appeal the reporting requirement to EPA, and the Agency could only exercise the supplemental reporting authority during the review period.

i. Processor reporting. In EPA's preferred approach, proposed on August 15, 1980, persons would be required to notify the Agency 90 days before they processed substances which were previously exempt from TSCA reporting. Specifically, this requirement would apply to processors of chemical substances manufactured without a commercial purpose (byproducts); substances manufactured or imported for research and development or test marketing; substances manufactured or imported as pesticides, tobacco or tobacco products, nuclear materials, firearms or ammunition, foods, food additives, drugs, or cosmetics; and substances manufactured before January 1, 1975, and not processed after that date or reported for the TSCA Inventory.

j. Possession or control. Section 5 requires that notice submitters include in their notices test data that was in their "possession or control." In the January 10 proposal, EPA defined "possession or control" to mean in the possession or control of (1) the submitter, or (2) any subsidiary, parent company, or subsidiary of the parent company, if the subsidiary, parent company, or subsidiary of the parent company was involved in commercializing the new chemical substance. Information is in the possession or control of a company if it is in company files, commercially available data bases to which the company has purchased access, or files maintained by employees associated with the commercial development of the new chemical substance.

3. Economic Impact of Proposed Rules

To evaluate the potential economic impact of proposed section 5 notice requirements, EPA requested that ICF Incorporated analyze the various provisions of the proposed rules and estimate their potential effects on the chemical industry. The ICF report, "Economic Impact Analysis of Proposed Section 5 Notice Requirements," served in part as a basis for this draft Regulatory Analysis. The Economic Impact Analysis is being published along with the Regulatory Analysis.

The ICF analysis incorporates the estimated costs for preparation of the October 16 proposed form originally developed by Arthur D. Little ("Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form," September 1979). The cost of completing the mandatory sections of the forms would range from $1,000 to $8,900 and costs for asserting and substantiating confidentiality from $900 to $6,400 (pp. 30, 33). However, ICF concluded that these costs are not the major source of the economic impact; rather, the indirect costs associated with uncertainty would generally outweigh the direct costs of complying with notice requirements. These indirect costs would reflect uncertainty about direct costs, possible trade secret disclosure, and possible restrictions on the use of new chemical substances.

According to the ICF analysis, section 5 requirements are likely to cause a short-run decrease in the number of new chemicals introduced as chemical companies shift their activities into "safe" chemicals. There may be a disproportionate burden for smaller companies, both because the volume of their new-chemical sales is lower and therefore produces fewer profits over which to absorb notice filing costs and because they may lack the legal and technical expertise to comply efficiently with section 5 requirements (pp. x, 98-100). The study concludes that the notice requirements will have the greatest effect on innovative segments of the chemical industry; products most likely to be affected are catalysts, surfactants, cyclic intermediates, rubber-processing chemicals, plasticizers, miscellaneous synthetic organic chemicals, adhesives and sealants, miscellaneous industrial inorganic chemicals, and plastics and resins (p. ix). Current data, however, do not allow quantitative estimates to be made of the effects of section 5 requirements on businesses of different sizes, different segments of the chemical industry, or the general rate of chemical innovation. According to the ICF analysis, it is doubtful that, even if the data were available, accurate quantitative predictions could be made.

4. Benefits of Proposed Approach

The proposed section 5 rules will establish clear, effective notification requirements and review procedures that will promote an efficient EPA review of new chemical substances. By presenting information in a standard format, the forms will allow EPA to determine rapidly whether a notice meets the statutory standard, to decide whether a substance requires detailed review or whether more information is needed for an adequate review, and, if necessary, to support regulatory action under sections 5(e) and 5(f). Without these rules, it would be difficult for EPA to conduct adequate reviews within the 90-day, or at most 180-day, review period.

In addition, the rules will give notice submitters a clear understanding of EPA's interpretation of key provisions of section 5 and of Agency notice review procedures. In doing so, they will greatly reduce uncertainty about the scope and nature of the Agency's premanufacture review program. For example, by defining such terms as "possession or control" and "importer," the rules will indicate who must report and how extensive the notices must be. In addition, the notice forms will lighten the burden for industry in the long run, once submitters have become familiar with the format and questions. Companies will not have to develop their own formats, and they will know exactly what information they must supply. As a result, submitters will be able to avoid costly delays due to submitting insufficient information.

Above all, the proposed rules will serve a fundamental purpose of TSCA and of section 5 -- to protect humans and the environment from unreasonable risks associated with new chemical substances. The rules will allow EPA to conduct prompt reviews of the hundreds of notices that it will receive every year, and when necessary to take regulatory action against substances of concern before they have harmed humans or the environment. The proposed approach, which will give EPA a minimum of information necessary for an adequate review, is the most consistent with the statute and with the needs of the Agency, the chemical industry, and the public.

II. MAJOR ISSUES

A. Reporting Requirements

Section 5(a) of TSCA requires manufacturers and importers to notify EPA 90 days before they manufacture or import a new chemical substance for a commercial purpose. In addition, EPA has proposed that certain processors be subject to section 5 notice requirements (see Section II(I), Processor Notification).

Section 5(d) of TSCA requires that notices submitted under 5(a) include, insofar as it is known to or reasonably ascertainable by the submitter, certain information on chemical identity, use, and exposure listed in section 8(a)(2) and any test data in the submitter's possession or control. The submitter must also include a description of any other data concerning environmental and health effects known to or reasonably ascertainable by him. Section 5 notices, supplemented by any other information obtained by EPA, form the basis of EPA's review of new chemical substances. Therefore, they should contain enough information for EPA to make a reasoned evaluation of risks associated with a substance, or to determine that more information is required for such an evaluation.

EPA has considered four approaches to implementing section 5 reporting requirements. The approaches differ in cost to the submitter and EPA and in level of detail required in a notice. They are presented below in order of increasing guidance to the submitter and increasing amount of information that EPA is likely to receive in the initial notice. In developing its proposed approach, EPA sought a process that would permit effective, consistent review and provide a basis for further regulation, without unduly burdening either the Agency or the submitter. For this reason, EPA prefers Option 3, the October 16 reproposal.

1. Options Considered

Option 1 -- "Do Nothing"

TSCA does not require EPA to issue premanufacturing notification rules. EPA could consider section 5 to be self-implementing and publish no guidelines or rules implementing the section. The Act provides some direction on the scope and applicability of the notice requirements, the information that must be included in the notices, the length of the notice review period, and the Agency's authority to regulate new substances. Under the "do-nothing" option, the argument would be that the Act is self-explanatory and that its instructions are sufficient to allow the mandated review.

Option 2 -- Minimum Guidance

Under Option 2, EPA would provide minimum guidance to establish general notification procedures and to clarify its interpretation of major provisions of the Act. The guidance would define section 5's applicability to importers, exporters, and processors; define the content of notices that met requirements of the statute; and outline procedures for handling confidential material. EPA would also specify categories of information it would require in the notices. Submitters, however, would have flexibility in choosing the format and level of detail of submissions so long as they were consistent with the Agency's general guidance. EPA partially adopted this approach in its Interim Policy, published May 15, 1979 (44 FR 28564). In the Economic Impact Analysis, the cost of submitting a notice under a minimum guidance policy in the long run is estimated to range from $1,011 to $7,486.

Option 3 -- Limited Form

Under this option, EPA would establish notification and review procedures, and it would require submitters to complete a limited notice form. The form would not include all the information that EPA could require under the Act, but only information sufficient in most cases for an initial review of a new chemical substance. The form, however, would also include a section of optional questions. During the review, EPA would identify substances for more detailed evaluation and possible regulatory action. If EPA needed more information from the submitter or from certain other persons for this detailed evaluation, it could obtain the information through its proposed supplemental reporting authority (see Section II(H), Supplemental Reporting). Instructions to the form would clarify information requirements and certain important provisions of the Act. Submitters could include in their notices additional information that they thought the Agency should consider in its review.

EPA proposed a limited form in the October 16, 1979, reproposal. Arthur D. Little (ADL) estimated that the costs of completing the mandatory sections of this form would range from $1,155 to $8,925. In commenting on the January 10 proposal, the Chemical Manufacturers Association (CMA) recommended an even more limited form. ADL estimated that completing the mandatory sections of the CMA form would cost from $955 to $5,550.

Option 4 - Detailed Form

In this approach, proposed January 10, 1979, EPA would specify notification and review procedures and require the submission of a form. In the January 10 form, the Agency attempts to collect information in sufficient detail for further regulatory action under sections 5(e) or 5(f). The detailed form also contains an optional section. Under this approach, the Agency would specify which optional data would be most useful for its review. Detailed instructions would accompany the form. ADL estimated that the cost to complete mandatory sections of the January 10 form would range from $3,740 to $22,160.

The estimated costs of submitting mandatory information under Options 2, 3, and 4 are summarized in Table II-1.

TABLE II-1

ESTIMATED COSTS OF FULFILLING MANDATORY REPORTING REQUIREMENTS

Option	Cost
Option 2: Minimum Guidance[a]	$ 1,011- 7,486
Option 3:	
CMA Form[b]	955- 5,550
October 16, 1979 reproposal[b]	1,155- 8,925
Option 4:	
January 10, 1979 proposal[c]	3,740-22,160

[a] ICF, Economic Impact Analysis, Appendix A
[b] ADL, Estimated Costs of Reproposed Premanufacture Notice Form
[c] ADL, Impact of TSCA Proposed Premanufacturing Notification Requirements

2. Discussion

If the Agency adopted Option 1, it would not publish a clarification of the Act or regulations to implement section 5. Each notice submitter would interpret the terms of the Act. Under this option, the initial burden on submitters might be low, because they could notify EPA in the manner they considered least costly and most expedient. Because of the uncertainty associated with this approach, however, the burden on EPA and industry might be great in the long run.

The disadvantages of this approach, and of Option 2, have become clear during the operation of the premanufacture review program since it began in July 1979. The program has been operating under the Interim Policy of May 15, 1979. EPA recommends the use of the reproposed notice form, but does not make it mandatory. Under this policy, EPA has received more than 200 notices. From these notices, the Agency has concluded that the language of the Act by itself does not provide sufficient guidance and that submitters often do not provide known or reasonably ascertainable information necessary for an adequate review. In a few cases, EPA has returned submissions as incomplete, a time-consuming action for both the submitter and the Agency. The resulting delay may cost the submitter his competitive advantage since the review period does not begin until a complete notice is submitted. In many other cases, EPA has found it necessary to go back to the submitter for information that should have been included in the initial notice. In such cases, EPA may have to extend the 90-day review period under section 5(c) to have enough time for an adequate review. Even when requests for more information do not lead to an extension of the review period, they require considerable Agency and industry resources.

In addition, the uncertainty that accompanies Option 1 imposes a substantial burden on the submitter. Without regulations implementing section 5, industry would have no guidance on the nature or scope of EPA's premanufacture review procedures. Submitters could learn only through experience what data EPA considered necessary for its review; how the Agency interpreted key provisions of the Act; and when it might seek additional information during the review period, either voluntarily or under section 8 or 5(e).

The cost of Option 1 is difficult to estimate, because the information submitted would depend on the submitter's interpretation of the requirements of the Act, and on the submitter's estimates about what information EPA would consider acceptable. The initial costs might be low, but in this case the likelihood of delay might be great. The cost of delay, and of the general uncertainty associated with this option, could slow new chemical innovation. The economic well-being of submitters, the growth of the industry, and its competitiveness with foreign industry might be affected.

To avoid the problems of Option 1, which depends on the submitter's interpretation of the Act, the Agency could publish minimum guidance, as in Option 2. More appropriate information might be submitted under this approach, improving the quality of the Agency's review, reducing the number of incomplete notices, and reducing the number and frequency of EPA requests for additional information. Reporting guidance for submitters would continue to be flexible. This approach would eliminate some of the uncertainty under Option 1 and thus reduce delay and other costs. In many respects, this approach was adopted in the Agency's Interim Policy.

Despite the advantages of this approach, EPA has found that minimum guidance does not eliminate inconsistent presentation of data. Under the Interim Policy, many submitters have chosen to use the October 16 form, in full or in part. Where they have not, the notices are submitted in different formats. The Agency must then expend limited resources organizing information for its review. These resources would be better spent on the review itself. Given the statutory time constraints, the quality of review may suffer. Inconsistent format and content also make it difficult for the Agency to develop a data base, which could be used in the future analysis of individual substances and in assessing the program as a whole.

To reduce the burden on the Agency and to ensure that it receives the data needed for its review, EPA could develop a notice form together with an instructions manual. Options 3 and 4 take this approach. The forms and instructions would specify requirements more exactly than minimum narrative guidance could, and they eliminate much of the uncertainty of the other options. Consistent format allows the submitter to establish information gathering and formatting procedures to minimize cost. In addition, EPA has found under the Interim Policy that the use of the October 16 form expedites and promotes the consistency of Agency review. The frequency of delays because of incomplete submissions is minimized, and additional information requests during the review period occur less often and are more focused.

For these reasons, EPA prefers the use of forms, as in Options 3 and 4. Forms can vary in the amount and level of detail of required information and in the type of optional material. In general, the more data the Agency receives, the higher the quality of its review, but the greater the initial cost to the submitter. At the same time, the more detailed the form, the less likely it is that EPA will have to go back to the submitter for further information, but the more likely it is that the submitter will provide EPA with information not needed for its review. In developing a form, EPA has attempted to balance its needs for conducting an adequate review against the burden to submitters of reporting unnecessary information.

A notice form could require information sufficient for a detailed review and possibly for regulatory action under section 5(e) or 5(f), it could require information sufficient for only an initial screening, or it could simply organize information explicitly required by the Act. In January 10, 1979 (Option 4), EPA took the first of these three approaches; in October 16, 1979 (Option 3), it took the second.

Proposed January 10 form: The notice form proposed in January required information on the identity of the submitter; and the specific identity of the new chemical substance; and information on production, use, and human and environmental exposure. Submitters were also required to include test data in their possession or control. In addition, the form had a lengthy optional section.

The costs of filling out the mandatory sections of the January 10 form were broken down by EPA's economic contractor, Arthur D. Little. These costs, excluding costs of asserting and substantiating confidentiality, are given in Table II-2.

TABLE II-2

ESTIMATED COSTS OF COMPLETING MANDATORY JANUARY 10 FORM

Section of Form	Cost
Part I: General Information	$ 840- 2,860
Part II: Risk Assessment Data	
Section A: Physical and Chemical Properties, Environmental Fate Characteristics, and Effects Data	900- 4,800
Section B: Exposure from Manufacture	800- 6,400
Section C: Exposure from Processing Operations	600- 6,400
Section D: Exposure from Consumer Use	600- 1,700
Total	3,740-22,160

Source: ADL, Impact of TSCA Proposed Premanufacturing Notification Requirements, p. V-17.

Many industry commenters suggested that the January 10 form was excessive in scope and in level of detail. They argued that much of the data required in the form would not be available at the time of submission, that the cost of developing data would impose an unreasonable burden on submitters, and that EPA lacked the statutory authority to require much of the information in the form. Several industry commenters submitted alternative forms, which generally reflected a narrower interpretation of EPA's statutory authority and its data needs. CMA, for example, recommended a form that reduced both the scope and the level of detail. Among other changes, the CMA form made optional questions concerning workplace concentrations, manufacturing process information, rates and amounts of release, and consumer exposure.

Proposed October 16 form: In response to these comments, EPA proposed a revised form on October 16 (Option 3), in which it reduced the data requirements of the January 10 form. These reductions do not reflect a determination by EPA that it lacks statutory authority to require additional information. Rather, they reflect two major objectives: (1) To obtain adequate information to permit at least a preliminary assessment of the risks associated with the manufacture, processing, distribution in commerce, use, and disposal of a new chemical substance, and (2) To achieve this objective at a minimum cost to persons submitting notices. In revising the notice form, EPA considered the minimum information and level of detail necessary for a preliminary assessment, the likely availability of such information, and the associated costs.

Arthur D. Little estimates for completing the mandatory sections of the October 16 form, not including costs of asserting and substantiating confidentiality, are given in Table II-3.

This revision reduced the cost of the January 10 proposed form by 50-60%, significantly lessening the burden on industry although still providing EPA with sufficient information to make an initial screening of new chemical substances. In the October reproposal, EPA rejected the minimum information form recommended by CMA. This form further reduces the cost of reporting by 20-30%, but it does not provide information in areas critical to EPA's evaluation of new chemical substances.

TABLE II-3

ESTIMATED COSTS FOR COMPLETING MANDATORY OCTOBER 16 FORM

Section of Form	Cost
Part I: General Information	$ 275-2,125
Part II: Human Exposure and Environmental Release	
Section A: Industrial Sites Controlled by Submitter	275-2,100
Section B: Industrial Sites Controlled by Others	0-1,200
Section C: Consumer Exposure	0- 800
Part III: List of Attachments	
a. Physical/chemical properties	150- 600
b. Health and environmental effects data	300-1,400
Part IV: Federal Register Notice	75- 300
Clerical costs	80- 400
Total	1,155-8,925

Source: ADL, Estimated Costs for Preparation and Submission of Reproposed Premanufacture Notice Form, p. 38.

Comparison of information required by forms: Information on manufacturing processes can be used to illustrate the different levels of detail in the various forms, and to explain the differences in cost. The January 10 proposed form required the submitter to provide a detailed schematic flow diagram illustrating each manufacturing and processing operation he intended to conduct (Part I, Section E). According to ADL (Impact of TSCA Proposed Premanufacturing Notification

Requirements, p. V-10), this diagram would require 4-40 technical hours ($100-$1,000) to prepare, plus 2-8 clerical hours and 2-4 legal and managerial hours. In the reproposal, in an effort to simplify the form and reduce the reporting burden, EPA deleted several specific requirements. The revised form does not require description of the type of process equipment, the components of each process stream, and process parameters. Rather, it requires a simplified block diagram (Part 2, Section A, Subsection 2) that provides a basic understanding of the manufacturing process necessary to identify potential exposures. According to ADL, this abbreviated diagram would require 1-24 technical hours ($25-$600) to complete, plus several clerical and managerial hours (Estimated Costs for Preparation and Submission of Reproposed Premanufacture Form, p. 34).

The block diagram as proposed in October considerably reduces the burden on the submitter. EPA, however, believes that it cannot eliminate a mandatory block diagram entirely, as the CMA form does. In its review of notices under the Interim Policy, EPA has found the block diagram necessary to make qualitative estimates of potential workplace exposure; to make quantitative estimates of the amount of new chemicals and byproducts released; to validate estimates provided in other parts of the form; and to provide supplemental information where no data are provided in other parts of the form (for example, on composition of release streams or the amount released to the environment). Under the Interim Policy, when EPA has not received a block diagram in a notice, Agency reviewers have in most cases found it necessary to draw one themselves on the basis of 1- to 2-hour telephone conversations with the submitter. In most of these cases, the necessary information was readily available to the submitter. It clearly would have been more efficient and less expensive if the submitter had provided the diagram in the first place.

In other ways, the information requirements of the January 10, the October 16, and the CMA form bear essentially the same relationship. The January 10 form, for example, requires specific estimates of the magnitude, duration, and frequency of worker exposure. The revised form requires significantly less detailed estimates and provides ranges for reporting workplace concentrations. The CMA form makes all information on workplace concentrations optional. In the same way, the January 10 proposed form requires specific estimates of environmental release data, including stack parameters, concentrations, and daily and hourly discharge rates. The October 16 proposed form requires only total release estimates. The CMA form confines quantitative release estimates to an optional section.

In all these areas, EPA reduced the reporting burden in the January proposal without seriously reducing its ability to make an initial assessment of the risks associated with new chemical substances. In cases where EPA needs additional information for a more complete assessment of risk, the Agency would require supplemental reporting. However, to reduce the requirements further, as in the CMA form, would severely restrict EPA's ability to make even an initial assessment and would lead to frequent requests for further information.

One major cost in both the January 10 and the October 16 proposed forms is the retrieval, organization, and attachment of health and safety data. ADL estimated that providing health and safety data in the January form would cost from $900 to $4,800. In the October reproposal, EPA significantly reduced this cost by eliminating specific questions on evaluations and assessments of test data in the section on physical and chemical properties and health and environmental effects (Part II, Section A). In its place, the form requires submitters to attach this information with the notice. The cost of submitting these attachments, would range from $450 to $2,000, according to ADL estimates.

In reducing the cost of providing health and safety data, the revised form has not changed in any way the basic requirement in section 5(d)(1)(B) of TSCA that the submitter include in the notice all health and safety data in his possession or control. Because of the statutory requirement to submit these data, any reporting scheme would involve these costs. The October reproposal, in fact, reduces the costs of retrieval, organization, and submission of health and safety data to a minimum. Because of this, the costs of providing health and safety data under Option 3 are no greater to the submitter than those of Option 1 or 2.

3. Preferred Approach

EPA's preferred approach is Option 3, the "limited form" option, using the October 16 reproposed form. This form will supply information necessary for a preliminary assessment of risks associated with most new chemical substances. The cost of completing the form will not be substantially greater than supplying information under Option 2, and costs will decrease as submitters become more familiar with the form. Although innovation might be slowed initially, long-run costs will be minimized once procedures for reporting have been established. The increased certainty about what data must be submitted will mean fewer delays, fewer and more specific supplemental data requests, and more efficient Agency review. EPA's burden will be minimized by established review procedures; more complete and consistent review will result.

Option 3, with the October 16 reproposed form, balances the cost of compliance for industry with EPA's need for detailed analysis. A limited form with guidance is sufficient for an initial screen of new chemical substances, and it reduces the burden on the industry by concentrating on those chemicals that clearly warrant further regulation. Only if EPA needs additional data will the expense of obtaining it be incurred. The use of a limited form is the most cost-effective approach to achieving Congress's goal of protecting the public from risks associated with new chemical substances without unduly impeding or creating unnecessary economic barriers to technological innovation.

B. Confidentiality

The confidentiality of information submitted to EPA is one of the most controversial issues associated with this rulemaking. EPA, mindful of both public and industry interests as well as procedures that would unnecessarily burden the Agency, has proposed a category approach to confidentiality. In this approach, submitters would assert and substantiate claims of confidentiality by linking the information claimed confidential to certain categories of information established by EPA. The disclosure policy regarding chemical identity as part of health and safety studies reflects this attempt at balancing conflicting interests as well. The following section discusses various approaches EPA considered to accomplish the goals of public disclosure and protection of traditional trade secret information.

1. Mechanics

The mechanics of confidentiality are the procedures for asserting and substantiating claims of confidentiality. EPA considered three options -- Option 1, the January 10 proposal; Option 2, the October 16 reproposal; and Option 3, the approach of the Interim Policy of May 15, 1979. The Agency has stated that, under any of the options, documentation submitted to substantiate confidentiality claims may be treated as confidential business information.

Option 1 -- January 10 Proposal

Submitters claim each confidential item individually by checking a box adjacent to the entry on the form. Submitters can also claim information confidential in attachments to the form. They would do this by designating the information as confidential on the attachment and providing a copy of the attachment with the information claimed confidential deleted so that this copy could be placed in the public file.

Submitters would substantiate claims of confidentiality for chemical identity and health and safety study information by answering two series of questions. Other information claimed confidential in the notice would be substantiated by the submitter when requested by the Agency.

Option 2 -- October 16 Reproposal

In the October 16 reproposal, submitters could assert claims of confidentiality by category. Submitters would assign items to the categories provided by the Agency by answering questions that explained the reason for including this information in the category. Substantiation would be by category of information as well; submitters could substantiate most claims by signing a certification statement on the form. However, they would have to substantiate chemical identity and information that did not fall within the categories provided by the Agency by responding to a series of questions.

Option 3 -- Minimum Guidance

Under Option 3, the submitter asserts his claims of confidentiality by clearly identifying confidential business information in the notice. Substantiations would not have to be submitted with the notice. Where EPA required substantiation, it would ask the submitter by letter a series of questions on each category of information claimed confidential. The submitter would substantiate the claims by responding to the questions within 15 days.

Discussion and Preferred Option

Although there are many variations of these options, described in Part II of the Economic Impact Analysis, these three options represent the basic choices available to the Agency.

In the October 16 reproposal, EPA explained that revision of the January 10 proposal was based on Agency experience with notices submitted under the Interim Policy, comments received on the January 10 proposal, the frequency of Freedom of Information Act (FOIA) requests, the need for Agency review of confidentiality claims, and Agency consideration of public and private interests in disclosure. The Act itself, in section 14, indicates a Congressional emphasis on disclosure of health and safety data and nondisclosure of traditional trade secret information. The category and substantiation scheme reflects this Congressional intent by placing a light burden on industry to claim and substantiate information of a commercial nature while requiring a more detailed substantiation for information relevant to health and safety information.

As noted in the Economic Impact Analysis (p. 126), the total amount of information required under the January and October approaches does not differ significantly. However, the January 10 proposal requires the submitters to expend greater effort in substantiating a claim, because they generally must answer more substantiation questions; the October 16 reproposal with its category and linkage approach, requires greater effort in asserting a claim. EPA prefers the second approach because it focuses the submitter's attention on the relationship among his confidentiality claims, which may make it unnecessary for him to make as many claims to protect his proprietary interests. Option 2 also provides a basis for a less duplicative substantiation. In Option 2, the Agency designated categories of information based on the information most commonly claimed as confidential since the premanufacture program began. For information that EPA has included in a category, the submitter may assert his claim by marking a single box X rather than by searching through the forms and individually marking every piece of related information to be claimed confidential. If the information has not been included in the category by EPA, the submitter marks the item separately and explains how its disclosure would reveal confidential business information.

By using the category approach, Option 2 significantly reduces the information required for substantiation and allows the submitter to avoid duplication. Also, under Option 2 EPA will review all substantiations for items in a notice at one time. Under Option 1, EPA might receive requests for different information in the same notice at different times. This would necessitate several reviews of the same notice by EPA.

The different degrees of burden for substantiation reflect different balances between the interest of industry in protecting proprietary information and the public's interest in protecting itself and in effectively participating in the review process. Option 2 would eliminate the need for submitters to supply additional substantiation information to the Agency, which would reduce costs and time delays. This approach is also intended to lessen the submitters' uncertainty as to the kind of substantiation the Agency would find acceptable and upon which it would make a determination not to release data claimed confidential. The unstructured approach of the January 10 proposal (Option 1) may seem to involve lower initial costs, but the increased cost due to submitter's uncertainty about Agency standards, the need for repeated Agency contact to determine the basis of the submitter's claims, and the submitter's need to provide additional information all increase these initial costs. Therefore, EPA prefers Option 2, the October 16 proposal.

2. Timing of Substantiation

Whichever format was provided for asserting and substantiating claims of confidentiality, the Agency would also have to decide when to require the substantiation. EPA has considered three approaches to this issue.

Option 1 -- January 10 Proposal

The January 10 proposal requires that submitters substantiate health and safety study information and chemical identity with the notice. Other items can be substantiated when EPA requests it, although EPA encourages submitters to substantiate all claims of confidentiality when the notice is submitted.

Option 2 -- Section 5(d)(2) Notice Option

This option requires substantiation of claims of confidentiality for chemical identity, categories of use, and test data at the time the notice is submitted. EPA, therefore, would know whether the information could be published in the 5(d)(2) notice. Other information, if claimed confidential, would have to be substantiated if requested, although again EPA encourages substantiation with the notice.

Option 3 -- October 16 Reproposal

The reproposal requires substantiation of all information claimed confidential when the notice is submitted.

Discussion and Preferred Option

The preferred scheme, Option 3, places emphasis on the timely release of data necessary for public oversight while safeguarding traditional trade secret data. As the proposed Economic Impact Analysis states, substantiating all types of information claimed confidential in the notice at the time of submission by the October procedures (Option 3) is less costly to the submitter than narrative substantiation under the other options. Not only is Option 3 less costly to the industry, but it provides many benefits to the Agency as well as the public. It allows the Agency to review all claims at once and to see the pattern and rationale behind confidentiality claims, giving the Agency insight into the needs of the chemical industry. It eliminates the need for multiple requests for information and provides clear guidance to industry regarding Agency standards for disclosure of nonconfidential information. The short notice review period provided by section 5 and the interest Congress displayed in public participation in the review process dictate an approach that will allow the Agency to review claims of confidentiality in a timely manner. Without substantiation in the notice, the Agency would never be in a position to release nonconfidential data to the public so that it could participate in the notice review process. Finally, the Agency needs substantiation information at submission to reply promptly to Freedom of Information Act (FOIA) requests. Commenters on the October 16 reproposal suggested that FOIA requests would be infrequent, and therefore early substantiation would be unnecessary. In fact, since the premanufacture review program began in July 1979, public interest groups have regularly made FOIA requests for notices. For all these reasons, therefore, EPA proposed substantiation at the time the notice is submitted.

3. Generic Information

If submitters claim information of particular public interest as confidential, the Agency has proposed that "generic" or masked information be provided to the public so that at least some information is available. Some of the Agency's earliest section 5(d)(2) notices were totally devoid of information, which made public participation in review of those notices impossible. The following options have been considered:

Option 1 -- January 10 Proposal

The January 10 proposal required submitters to develop a generic name for chemical identity according to Agency instructions. If categories of use were claimed confidential, generic descriptions of that information would also be required. EPA did not give specific guidance about an acceptable generic or masked category of use description.

Option 2 -- October 16 Reproposal

Procedures for developing four types of masked information are provided in the reproposal: manufacturer's identity, categories of use, chemical identity, and physical and chemical properties. If these procedures do not provide adequate protection for information claimed confidential by the submitter, the submitter may provide alternative masked information suitable for public disclosure either in the FEDERAL REGISTER or in the public docket.

Option 3 -- No Masked Data

Under this option, EPA would not require generic substitutes for confidential data. No masked data would be published in the FEDERAL REGISTER or placed in the public docket.

Discussion and Preferred Option

Section 5(d)(2) of TSCA lists certain information that EPA must publish in the FEDERAL REGISTER 5 days after receipt of a premanufacture notice. It is clear that the purpose of this notice is to inform the public that a notice on a new chemical substance has been submitted for review and that the public should come forward with any information it has about the substance and participate in Agency review.

Option 3 does not provide adequate notice to the public. Option 1, as noted in the comments to the January 10 proposal, does not give sufficient guidance as to categories of use information, nor does it give the submitter the flexibility to provide generic information unique to his confidential business needs. Option 2 provides sufficient information for the initial notice to the public while recognizing the industry's need to protect confidential information. As the proposed Economic Impact Analysis notes, Option 2, with clear guidance as to what generic descriptions will meet Agency standards, is the most effective approach for reducing industry uncertainty and concerns about any arbitrariness in the Agency's treatment of generic or masked information.

4. Disclosure of Chemical Identity

The Agency's January 10 proposal included an approach for disclosing chemical identity that has been claimed confidential. As the Agency noted on January 10, chemical identity is underlying data to a health and safety study. However, EPA recognizes the special significance this information may have, especially during the early stages of development of the new chemical substance. EPA considered three options regarding timing of disclosure of chemical identity. Consistent with section 14(b), under all the options EPA would not disclose chemical identity if it revealed confidential process information or proportions of a mixture.

Option 1 -- Disclosure at the time of notice submission

Under this option, chemical identity would be published in the section 5(d)(2) notice announcing receipt of the premanufacture notice, and health and safety data would be made available to the public. At commencement of manufacture, the chemical identity would be entered on the Inventory and would not be masked by a generic name.

Option 2 -- January 10 Proposal

Because of the special importance of chemical identity, the January 10 proposal provided that it would not be disclosed until commencement of manufacture. The chemical identity would go on the Inventory at commencement of manufacture and would not be masked by a generic name.

Option 3 -- Disclosure at Distribution in Commerce

Several commenters suggested that chemical identity should not be disclosed until distribution, which would be sometime after manufacture for a commercial purpose. Under this approach, a generic identity would be initially entered on the Inventory; after distribution began, the chemical identity would go on the Inventory.

Discussion and Preferred Option

Section 14(b) provides that data from health and safety studies may be disclosed to the public notwithstanding the non-disclosure provisions of section 14(a). The legislative history and scientific practice argue that chemical identity is part of a health and safety study; as such it should be disclosed. However, section 14(a) also indicates the concern for protection of proprietary data. Therefore, the Agency prefers a compromise position that would prevent disclosure during the early stages of development and commercialization, and that would protect confidential chemical identity until the time of manufacture or some reasonable time thereafter. The January 10 proposal (Option 2) provides an approach that is consistent with this policy. This approach limits access to data that the public would have under Option 1, but the Agency hopes to reduce the effect of this limitation by providing meaningful generic information indicating the toxicologically significant aspects of the molecular structure of the chemical identity claimed confidential.

Option 3 has some of the advantages of Option 2, but it creates uncertainty because the "commencement of commercial distribution" is difficult to define, and it would require submitters to notify EPA when they first distributed a substance commercially as well as at commencement of manufacture. To eliminate these difficulties, EPA is considering the possibility of protecting the confidentiality of chemical identity underlying a health and safety study for a set time after commencement of manufacture -- for example, six months -- by which time the manufacturer would have had adequate time to begin commercial distribution. With this modification, the submitter would not have to notify EPA at commercial distribution. This approach, however, would still have some disadvantages of Option 3. EPA would have to conduct an additional review of confidentiality claims when the substance was first distributed commercially to determine if disclosure of chemical identity would reveal confidential processes or proportions of a mixture. This approach also postpones the public's access to these data to a point at which it may be less likely to prevent exposure or distribution of the new chemical substance. EPA solicits public comment on the appropriateness of this approach as an alternative to the January 10 proposal.

C. Incomplete Submissions

A premanufacture notice must meet certain explicit standards. If the submission does not meet these standards, it is incomplete and the 90-day review period will not start. Section 720.34 of the January 10 proposal explained EPA's interpretation of section 5 notice standards, classified various types of deficiencies, and described the procedures EPA will follow in handling deficient notices. The proposed criteria for defining incomplete submissions are drawn either directly from TSCA or from other parts of the proposed premanufacture notification rules.

In developing its approach to incomplete submissions, EPA has considered the four options discussed below.

1. Options Considered

Option 1 -- January 10 Proposal

In section 720.34 of the January 10 proposal, EPA identified two kinds of deficiencies: (1) Major deficiencies that prevent the review period from starting; (2) Minor deficiencies or errors that stop the clock during the notice period. The distinction between major and minor deficiencies is determined by certain criteria set out in the proposal. If EPA identifies a major deficiency in a submission at any time during the review period -- such as failure to supply information required in the notice form if it is known to or reasonably ascertainable by the submitter -- the Agency may return the submission. In this case, EPA would consider no notice to have been submitted. When a submission was received that did meet the criteria, the 90-day review period would begin.

If EPA identifies a minor deficiency, within 30 days after receipt of a submission it may request a submitter to correct the deficiency. Examples of minor deficiencies are failure to date the notice or a typographical error that renders an entry unclear or ambiguous. The Agency will suspend the review period until the submission is corrected. If the submitter does not make the correction within 30 days, EPA may determine that the submission does not meet the standards of the Act. Also, if EPA discovers during or after the review period that the submitter provided false or misleading information, EPA can treat the submitter as not having complied with the notice requirements of section 5. Therefore any manufacture or import may be in violation of TSCA and subject to penalities of sections 15 and 16.

Option 2 -- Appeal Procedures

Option 2, a modification of Option 1 reflecting concerns expressed by industry, narrows EPA's criteria for determining that a submission does not meet the standards of the Act. Under this option, EPA would notify the submitter within 30 days of receipt of a submission if it was incomplete (major deficiency), or if it contained errors (minor deficiency). If the submission was incomplete, the notice review period would not begin until the deficiencies were remedied. Submitters could appeal an EPA finding that a submission did not meet the Act's requirements. For errors, the review would not stop, although submitters would be encouraged to correct the errors.

Option 3 -- Case-by-Case Approach

Taking a case-by-case approach, EPA could find a submission insufficient to fulfill the requirements of section 5. However, no formal criteria or procedures would govern EPA's treatment of such submissions. If EPA found a submission incomplete, the review period would not start, and the submitter would not have any formal avenues of appeal. For errors in the submissions (e.g., typographical mistakes), EPA would take the same action as in Option 2.

Option 4 -- No Incomplete Submission Provisions

Under this option, if the submitter did not file a notice that met the Act's standards, EPA could require information under the proposed supplemental reporting authority. Commenters on the January 10 proposal also suggested that EPA could control the substance under section 5(e) pending the submission of the necessary information.

2. Discussion

Options 1 and 2 outline the criteria that EPA uses in determining whether a submission meets the statutory requirements. Notices must fulfill these criteria when submitted, or be corrected in a timely manner, before the review period begins. Under Option 3, submitters would also have a strong incentive to submit notices that meet the requirements of the Act, although they would not have clear guidelines about how EPA interpreted these requirements. The incentive of submitters to correct major deficiencies would be the same as in Options 1 and 2. Under Option 4, EPA could only request that deficient submissions be corrected. If submitters did not respond, EPA could use its proposed supplemental reporting authority or, in some cases, issue a section 5(e) order requiring additional data. However, these actions would expend considerable EPA resources, and the notice review period might be interrupted or extended.

Submissions in Options 3 and 4 are not held up to explicit criteria, and no clear distinction is made between major omissions and errors. In Option 4, there would be no guidance for submitters who must correct their notices. Without published criteria and procedures, industry would be uncertain about how submissions would be treated, and the possibility of inconsistency in Agency actions would increase.

Option 4 presents several special problems. If a person failed to submit a complete notice, EPA would accept the submission for review. However, to obtain the necessary information, the Agency might extend the notice period up to 90 additional days under section 5(c), issue a section 8(a) supplemental reporting requirement, or, in some cases, issue a section 5(e) order. Delays associated with these actions might have an adverse effect on the submitter's production schedule and marketing plans.

All four options will involve out-of-pocket expenses to prepare notices. The submitter would incur additional expenses under Options 3 and 4 if EPA required supplemental reporting or otherwise took action to get information. Option 2 carries an additional cost if submitters appeal an EPA decision that submissions do not meet statutory requirements; however, the right to appeal protects them from arbitrary action.

EPA's initial costs under Options 1, 2, and 3 are greater than under Option 4 because under these options the Agency must review notices for compliance. Option 3 perhaps involves the greatest initial cost for EPA because the Agency will have to handle notices on a case-by-case basis without formal criteria. Option 4 would at first involve the fewest EPA resources. But, potentially, it could be the most expensive for both EPA and industry, if EPA frequently used the supplemental reporting authority or otherwise took action to get information that should have been included in the initial submission.

Costs to society are highest with Options 3 and 4. EPA may not have enough resources to review and take action against incomplete submissions on a case-by-case basis. Therefore, under Option 3 the Agency may miss deficiencies in certain submissions, and therefore fail to learn of important information on potentially hazardous chemicals. In Option 4, submitters who fail to provide complete submissions might be subject to supplemental reporting rules or other action. However, EPA would be able to take relatively few of these actions. Thus, the Agency may pass over some problem chemicals for which deficient submissions are made; the public and the environment would suffer. Because Options 1 and 2 impose standards on submitters and commit EPA to reviewing section 5 notices for deficiencies, there is less chance that EPA will be unable to gather adequate information to evaluate potentially harmful chemical substances.

3. Preferred Option

EPA prefers an approach that sets out the criteria that submissions must meet for the notice review process to begin. Submitters, therefore, know the requirements, and the costs of preparing complete notices are well defined. Submitters will also know the delay likely to result from submitting information that does not meet the requirements. As explained earlier, costs to EPA are likely to be lower under options that set out clear standards for notices.

Options 1 and 2 incorporate the statutory requirements that a notice include certain information. A submitter is not in compliance with this section if his submission does not contain that information, as long as it is known to or reasonably ascertainable by him. An incomplete submission prevents EPA from conducting a proper assessment. Option 3 does not provide clear guidelines, and Option 4 does not provide any procedures to act on incomplete submissions. In this case, the content of notices would depend on industry's interpretation of the statute. EPA does not believe that Congress intended industry to make its own interpretations of the Act. Moreover, TSCA requires the submitter to provide the information specified; it does not place the burden on EPA to extract it.

Option 1 and Option 2 are similar, but Option 1 places the burden on the submitter, not EPA, to correct the submitter's errors in notices. Under Option 1 EPA can stop the review clock until the submitter corrects "minor deficiencies" affecting the clarity of the notice. This should not be burdensome to the submitter, because the deficiencies would be minor -- like a failure to date the notice -- and therefore easy to correct. EPA, of course, will not require the submitter to correct every error, but only those that make the notice unclear. Under Option 2, EPA would notify the submitter of the error within 30 days, but the review clock would not stop. The submitter would have less incentive to correct the error promptly. As a result, the burden for interpreting any ambiguity caused by the error would fall on EPA. Finally, the purpose of EPA's data-gathering authority under sections 8 and 5(e) is not to gather information necessary for an initial screen, but to require additional data based on the information initially provided.

Option 2, however, provides significant benefits for submitters. Under this option, EPA must notify submitters of a deficiency within 30 days of receipt of a submission. Therefore, submitters would know quickly if their notices met the minimum standards of the Act, and they would not be faced with the possibility that EPA could stop the review period after that time. Also, submitters could appeal an EPA finding that a submission did not meet the standards of the Act. EPA requests comments on this approach and other approaches to determine that submissions meet the requirements to begin the notice review period.

D. Customer Contact

Section 5 must contain certain information on processing and uses that is known to or reasonably ascertainable by the submitters. In some cases, submitters may not know about proposed methods of processing or uses, but this information is generally known to their customers. To get this information for a notice, submitters may have to contact potential customers.

EPA considered four options for defining the extent of the submitters' obligation to contact and gather information from customers.

1. Options Considered

Option 1 -- Provide Information from All Potential Customers

Option 1, section 720.20(e) of the January 10, 1979, proposal, requires notice submitters to contact persons who they have reason to believe would purchase the new chemical substance. Submitters must ask potential customers to complete a Processing and Consumer Use Form. The Form requests information on exposure and environmental release resulting from processing, use, and disposal. In addition, submitters must list in their notices the names and addresses of the customers they contacted, and they must identify the persons who provided them information or who were sending it directly to EPA. Customers may claim any information they provide confidential.

Customers are under no legal obligation to respond to the submitter's request for information. When customers do not respond promptly, or when they do not respond at all, EPA does not expect submitters to delay sending their section 5 notices. Failure of customers to provide information either to the submitter or to EPA does not affect the beginning of the notice review period.

Two exceptions apply to these mandatory customer contact requirements. Submitters may contact a sample of customers if they believe that a significant number of customers will provide duplicative information. And submitters need not contact any person who they believe will not provide substantive information required in the notice form.

Option 2 -- Report Number of Persons with Firm Commitment to Purchase Substance for Unknown Uses and Volume of Substance to be Sold to These Persons

Option 2 was discussed in the October 16 reproposal as an alternative to Option 1. Option 2 has no mandatory customer contact provision, no customer list, and no Processing and Consumer Use Form. Instead, submitters are required only to report the number of committed customers intending to use the substance in ways not known to them and to report the percentage of production volume allocated to those customers during the first three years of production. The customer definition is narrowed from that of Option 1 to persons who have contracted to purchase, submitted a purchase order for, or made a firm commitment to purchase the new chemical substance for uses unknown to the submitter.

Under this option, if EPA needs additional use information, it can go back to the submitter for the names and addresses of the customers. EPA can then contact the customers. These contacts will be limited to situations where EPA needs information for a detailed assessment.

Option 3 -- Provide Information in Option 2 Plus a Customer List

Option 3 is Option 2 with a customer list added. It was also discussed in the October 16 reproposal as an alternative to Option 1. Submitters must include with their notices a list of customers who have contracted to purchase, submitted a purchase order for, or made a firm commitment to purchase the new chemical substance. EPA may contact prospective customers directly when it finds that use information or other information in the section 5 notice is not adequate to assess potential exposure.

Option 4 -- No Mandatory Customer Contact

Option 4 eliminates the customer contact provisions. Submitters are under no obligation to send a customer list to EPA, or to ask customers to submit information on uses of the chemical substance. However, submitters still are required to complete section B of the reproposed form, "Industrial Sites Controlled by Others." In this option, as in Options 2 and 3, EPA, not the submitter, will obtain customer use information when it is needed for detailed review.

2. Discussion

Option 1 is the most costly option for submitters. The comprehensive definition of customers, which includes potential customers as well as those who have made a firm commitment to purchase, will require submitters to keep up-to-date files on committed customers and customer contacts. Many companies may not ordinarily keep such records. Thus, submitters may incur additional expenses to have this information on hand. Submitters will also incur costs to contact customers.

Submitters in Option 2 and 3 will also incur certain administrative costs, but these costs will be less than in Option 1. With the customer definition narrowed to committed customers, these options should not in most cases increase recordkeeping costs for submitter. Generally, the customer information requested in Options 2 and 3 is in a company's records. Submitters will only have to prepare and submit this information. (Under Option 3, submitters may incur the cost of preparing a customer list.) Under Option 4, submitters have no obligation to submit customer information, and therefore will incur no costs associated with mandatory customer contact. Because there is no Processing and Consumer Use Form in Options 2, 3, and 4, submitters will not incur the costs of contacting customers. Instead, EPA will incur these costs.

Option 2 is less expensive to submitters than Option 3 because it requires them to give EPA the names and addresses of customers only when the Agency needs to contact them for use information -- which EPA may require for chemicals subject to detailed review. Since only a small percentage of new substances undergo detailed review, submitters in most cases under Option 2 will not have to provide EPA with a customer list. Under Option 3, however, submitters are required in every case to send a customer list with their section 5 notice. Therefore, they may incur the expense of providing EPA information unnecessary for its review.

Although Option 4 does not require submitters to contact customers or to submit customer information, submitters may still incur expenses associated with customer information. Under this option, EPA will have to go to submitters for customer information needed for its review. Some submitters may provide EPA with this information voluntarily. In other cases, EPA may have to take action under the proposed section 8(a) supplemental reporting authority to get information from either the submitter or processors.

Option 1, which requires customer contact, should eliminate delays when customers voluntarily submit the Processing and Consumer Use Form. Under Options 2, 3 and 4, EPA will have to get use information from customers, possibly leading to delays in the review process that may affect the introduction of new chemicals into commerce. Delay is more likely in Options 2 and 4 than in 3, because in these options EPA must go first to the submitter to get the names of customers before it contacts them. This will not be necessary in Option 3 because the submitter is required to provide a customer list. If a submitter or customer is reluctant to provide EPA with information, the action EPA takes to obtain this information may make it necessary to extend the review period under section 5(c).

Initial costs to customers are likely to be greatest under Option 1, because in most cases they will be asked to complete a Processor and Customer Use Form. On the other hand, delays are likely to occur less often under this option. Under Options 2, 3, and 4, EPA will request customer information only on chemicals undergoing detailed review. Customers in the no-mandatory-contact options, therefore, will not in every case incur costs to provide EPA with use information.

Customers face the risk of trade secret disclosure when they provide use information to the submitter (Option 1) or to EPA (Options 2, 3, and 4). This threat to confidentiality may affect customers' responsiveness, especially if Option 1 is adopted. The fear of disclosure of the customer lists in Options 1 and 3 may also affect customers' responsiveness.

Administrative costs to EPA and the likely extent of its efforts to obtain customer information must be considered in an evaluation of the options. Option 1 requires the least effort, because the submitter is responsible for contacting customers. But Option 1 may involve the highest administrative costs for EPA because the Agency must file, maintain, and protect the confidentiality of customer information on a routine basis, although it may need this information for only a small percentage of chemicals. In Options 2, 3, and 4, EPA will incur lower recordkeeping costs. The cost is highest for Option 3, where submitters are required to include customer lists with their section 5 notices.

The potential costs to society are greatest under Option 4. Because it will receive less customer information, EPA will be less able to protect health and the environment from the introduction of hazardous substances. Despite their differences, Options 1, 2, and 3 each give EPA the means to identify customers and to gather enough information to decide if detailed review is necessary. In this regard they afford greater protection to society than does Option 4.

3. Preferred Option

EPA prefers Option 2. Customer use information is usually necessary only for detailed review. Because EPA expects a small percentage of chemicals to undergo detailed review, it does not believe it is necessary to collect this information routinely, as would be done in Option 1. EPA also believes that it does not routinely require a customer list, which Option 3 provides. However, EPA does need enough customer information to determine whether processing and use is likely to cause a problem, or whether more information is needed. Option 3 would generally provide EPA with this information in the initial notice; Option 4 often would not.

EPA believes the information required from submitters under Option 2 gives the Agency adequate information for its initial review of new chemical substances. It would give EPA an understanding of how complete the use information is in the notice. In combination with other information in the notice, the customer information under Option 2 will help EPA decide whether or not to ask for additional use information from the submitters' potential customers. If EPA determines that it needs additional information, it can contact submitters and ask them to provide the names and addresses of their customers.

Option 2 is less burdensome to industry than Options 1 and 3. In Option 2, EPA will request more information only when it is necessary for detailed review, and the Agency will generally carry the burden of contacting the customer. Thus, submitters, their customers, and EPA would not be responsible for routinely gathering and maintaining information that is usually not necessary in the initial evaluation of a chemical substance. Also, EPA would not have to maintain files and protect the confidentiality of unused information, as it would under Option 1 and to a lesser degree under Option 3.

E. Importer Definition

Section 3(7) of TSCA defines "manufacture" to include "import." Therefore, importers are subject to all requirements of the Act that apply to manufacturers, including the notice requirements of section 5. In developing a proposed definition of importer for the purposes of section 5, EPA took into account the fact that import transactions vary in the number of parties involved and the methods of import. Some parties in the import process may be unaware of important information about the chemical substance, and, in some cases, no one party may know all the information of concern to EPA. Therefore, EPA has attempted to develop a definition that will ensure that the person who knows the most about an imported substance will be required to submit a notice.

EPA considered five alternative definitions of importer in this rulemaking. The major options are discussed below.

1. Options Considered

Option 1 -- Consignee

This option designates one person, the consignee, as responsible for notifying EPA of intent to import a new chemical substance. The consignee is the person to whom the goods are delivered. He may be any person, including a retailer or an agent, involved in the import transaction.

Option 2 -- Consignee, Who Would Obtain Information from Other Persons

Option 2 is the same approach as Option 1, but it also requires the consignee to contact other persons for information needed to complete the section 5 notice. These other persons include users and processors who can be identified and any agents, customhouse brokers, or importers of record. These persons would provide the consignee with the information, or they could send it directly to EPA. They would, however, be under no obligation to report the information to the consignee or EPA.

Option 3 -- Any Party Involved in the Import Transaction

Option 3 is the definition of importer in the January 10, 1979, proposal. This broad definition, adapted from the definition of the U.S. Customs Service of the Treasury Department, requires "any person who imports" to file the notice. Importers include the person primarily liable for the payment of duties, the consignee, the importer of record, the actual owner, and any transferee. Under the January 10 definition, each of the persons listed is responsible for ensuring that a notice is submitted to EPA. The definition does not identify one person responsible for submission of the notice.

Option 4 -- Principal Importer Responsible for Notice Submission

Option 4 was published in the FEDERAL REGISTER of September 23, 1980 (45 FR 63606) as a clarification of the January 10 definition (Option 3). This option uses the broad definition of importer in Option 3, but it specifies that the "principal importer" submit the section 5 notice. The principal importer is the first person who, knowing the new chemical will be imported, selects the chemical substance and the total amount to be imported. This person is likely to be a processor, user, or distributor of the chemical.

Option 5 -- Any Person Who Imports, or Knowingly Causes to be Imported, a Chemical Substance

Under this option, the importer is defined as any person who imports, or knowingly causes to be imported, a chemical substance. A person placing an order for a chemical substance in a domestic transaction would not "knowingly cause" the import of the substance unless he controlled the terms and conditions of import.

3. Discussion

As EPA stated in the Support Document accompanying the January 10, 1979 proposal, the importer definition should designate the person, or persons, who know the most about the nature and use of the import. Options 1 and 2 fail to do this. Instead they identify the consignee as the person responsible for submitting the notice. The consignee is often a retailer or agent, persons who ordinarily do not know information on the imports that is useful or necessary for an initial screen. If they did not know this information, or it was not reasonably ascertainable, they would not have to submit it.

Option 2 addresses this problem by requiring the submitter (the consignee) to ask for information from other parties, including future users and processors. Although the Option 2 submitter is often not the most knowledgeable party, he may obtain information valuable for EPA's review from others. Under Option 1, submitters may also find it useful to seek information from other more knowledgeable parties. However, without the requirement, they are less likely to do so.

Under Option 3, EPA ensures that the most knowledgeable person will be involved in the submission by making all parties to the import transaction responsible for notification. The notice submitted under this option would include all required information known to or reasonably ascertainable by any of the parties to the transaction. If this definition is properly implemented by importers, it should provide a complete notice with information sufficient for an initial screen by EPA.

However, the Option 3 approach may not be easy to implement. When several parties are responsible for preparing a submission, or contribute to its preparation, it may be incomplete. This may occur because of a disagreement among the parties, or because certain parties do not cooperate and provide necessary information. (The same problem can occur in Option 2, under which the consignee is obligated to contact other persons. It can also occur in Options 1 and 5 if the consignee or person knowingly causing import asks other persons for information.)

Commenters on the January 10 proposal argued that, by not naming a principal party responsible for submission, the Option 3 approach might not serve EPA's purposes. EPA would have no guarantee that the most knowledgeable person would be actively involved in the preparation of the notice, or that the parties to the transaction would cooperate effectively. In response to these comments, EPA is considering Option 4, which would not change the definition in Option 3, but would clarify it by specifying that only the "principal importer" be responsible for submitting the notice. Since the principal importer is the party who selects the imported substance and is usually a processor, user, or distributor of the chemical, information necessary for EPA's review should be known to or reasonably ascertainable by him.

Option 5 does not identify a specific party in the import transaction as primarily responsible for submitting the notice. The person who "imports or knowingly causes" a substance to be imported can be any one of several parties (e.g., agents, brokers). These persons do not necessarily know much about the chemical and its properties. Therefore, this alternative does not achieve EPA's goal that the most knowledgeable person submit the notice.

Commenters on the January 10, 1979, proposal also raised the issue of the responsibility of the notice submitter and others associated with the preparation of the notice under the joint-submission options. The Preamble to the January proposal states that, under the importer definition (here Option 3), each of the persons listed is responsible if he imports a substance for which EPA has not received a notice. However, it is not clear whether all parties to an import transaction share responsibility for the accuracy of the information in a notice, regardless of which one submits it. Option 2 also poses a liability question with respect to the adequacy and accuracy of the information. The consignee in this alternative gathers information for submission from future processors, users, and distributors and from persons actually involved in the import transaction. The consignee would be responsible for providing a complete submission; the consignee and others who contributed to the preparation of a notice would share in the liability if the information they provided was not accurate.

An advantage of joint notice submission, if it works properly, however, is the sharing of costs to prepare the notice by the persons involved in the import transaction. In Option 2 the consignee collects information from other parties. The cost of gathering and preparing this information, therefore, is shared by these persons, thus reducing the consignee's financial burden. Under Option 3, where all the parties are involved in the notice process, the responsibility for preparing the notice is presumably shared by the various parties. The disadvantages of this arrangement is the possibility of duplication of information and effort. With responsibilities spread among several persons, total costs may be greater than if one party is responsible for preparing and submitting the notice.

Under Options 1, 4, and 5, one importer party carries the burden of financing the submission. This is particularly burdensome to importers in Options 1 and 5, since the consignee and the person knowingly causing import are not necessarily the persons who know the most, or can most reasonably ascertain, information required by EPA for its review. If they gather information from other persons, their costs will be higher than those incurred by the principal importer (Option 4).

The risk of disclosure of trade secrets is possibly greater in Options 2 and 3, the joint-submission options. In Option 2, a consignee is responsible for gathering information from other persons. Information may be disclosed when he transfers it to EPA. In Option 3 all the named parties share responsibility for submitting a notice; therefore it is possible that confidential business information may be revealed during preparation.

Importers under Options 1, 2, 3, and 5 may wish to delay their notices until they have obtained information from other parties. If they do, they will have to delay import. But if they submit their notices before securing certain information, the review may be delayed. For example, if they cannot adequately identify the new chemical substance, EPA will find that the submissions do not meet statutory requirements. In this case, the review process will not begin. If they do not provide other information necessary for review, EPA may use the proposed section 8(a) supplemental reporting authority or, in some cases, section 5(e) to require importers to provide the necessary information. However, these actions expend EPA resources, and they involve delays that may have an adverse effect on the importers.

A disadvantage of the definitions in Options 1, 2, and 5 is that they are inconsistent with the U.S. Customs Service definition and with other definitions of importer under TSCA. Options 3 and 4, however, are consistent with the Customs Service definition, although broader, and with other TSCA definitions.

3. Preferred Option

EPA prefers the definition of importer in Option 3, which it proposed on January 10, 1979, and recently clarified in a notice in the FEDERAL REGISTER. This definition is consistent with other TSCA definitions and with the U.S. Customs Service definition. Option 3 makes all parties to the import transaction responsible. Under this option, EPA may be more likely to receive a submission that provides enough information for its review. If each party is responsible, each will have a strong incentive to see that any notice submitted is complete and accurate. The requirement should not be excessively burdensome, since submitters will only be required to submit information known to or reasonably ascertainable by them. On the other hand, because no single importer is designated as the submitter, this option may not serve EPA's purposes, as explained earlier. Therefore, the Agency is also considering Option 4, which clarifies the definition so that it requires the "principal importer" to submit the notice. In the notice of clarification, EPA solicited comment on this option.

F. Importer Contact of Foreign Manufacturers/Suppliers

To prepare a section 5 notice sufficient for an adequate review, importers of new chemical substances may need assistance from foreign manufacturers or suppliers. This requires a cooperative arrangement in which the foreign manufacturer supplies the information that the importer lacks. Since the foreign chemical industry is not regulated by the U.S. premanufacture program, its role in this process is voluntary. Cooperation by foreign industry will depend in part on the benefits the manufacturer expects to derive from entering the U.S. market, the relationship of the importer to the manufacturer, the availability of the information to the manufacturer, the resources needed to provide the information, and the manufacturer's concern over the risk of trade secret disclosure, which in part could result from differences between U.S. and foreign law protecting confidentiality.

The cooperativeness of foreign manufacturers and suppliers may depend on the availability of requested information and the extent of their concern for confidentiality. As the Economic Impact Analysis indicates, most foreign manufacturers are located in the European Economic Community and Japan. Although there are certain differences in their notification programs, the information requirements for new chemical substances in these countries generally are or will soon be similar to those under TSCA. However, foreign manufacturers may be reluctant, for reasons of availability, cost, or confidentiality, to cooperate with the importer.

Foreign manufacturers can protect trade secrets from disclosure during transit by submitting them directly to EPA. Nevertheless, there may be conflicts between their interests in secrecy and EPA's and the U.S. public's information needs. Therefore, foreign manufacturers, who are not legally obligated to comply with EPA's requirements, may sometimes be reluctant to submit information to EPA under section 5. Obviously, the absence of U.S. legal authority over foreign manufacturers is a controlling factor in contacts between U.S. importers and foreign manufacturers. EPA will depend on cooperation of foreign industry for this part of the premanufacture notification program to function.

Although the participation of foreign manufacturers and suppliers is voluntary, EPA can require that importers contact these persons and request that they submit information. EPA evaluated four approaches to the issue of importer contact of foreign manufacturers and suppliers.

1. Options Considered

Option 1 -- Mandatory Contact and January 10 Foreign Manufacturers/Suppliers Form

In this option, importers would be required to ask foreign manufacturers and suppliers to complete the Foreign Manufacturers/Suppliers Form proposed on January 10, 1979.

Option 2 -- Mandatory Contact and Shortened Form

Importers would be required to ask foreign manufacturers and suppliers to complete a Foreign Manufacturers/Suppliers Form consistent with changes in the domestic form proposed in the October 16, 1979, reproposal.

Option 3 -- Mandatory Contact for Health and Environmental Effects Data

Importers would be required to contact foreign manufacturers and suppliers for health and environmental effects data and risk assessments.

Option 4 -- No Mandatory Contact

Importers would not be required to contact foreign manufacturers or suppliers.

2. Discussion

The four approaches considered by EPA fall into two basic categories: mandatory contact and no mandatory contact. The mandatory contact alternatives, Options 1, 2, and 3, each require the importer to contact the foreign manufacturer. They differ in the amount of information the importer requests. The burden on the foreign manufacturer to provide information decreases from Option 1 to Option 3. Under Options 1 and 2, the importer provides the foreign manufacturer with a Foreign Manufacturers/ Suppliers Form, which he would complete and submit to the importer or directly to EPA. This form is shorter than the form that U.S. manufacturers and importers submit under section 5. It includes questions on manufacturer and supplier identity, chemical identity, production and marketing data, physical-chemical properties, and health and environmental effects data; it does not include questions on occupational exposure, consumer exposure, or environmental release. Under Option 3, the foreign manufacturer sends to EPA only health and environmental effects data and risk assessments.

Under Option 4, the importer is under no obligation to contact foreign suppliers and manufacturers. This approach works well for importers who do not require additional information for their notices. It poses a problem, however, for importers who need information for a complete submission. If the importer does not know the chemical identity, he will have to contact the foreign supplier or manufacturer for that information, regardless of a no-mandatory-contact provision. If he sends a section 5 notice to EPA without chemical identity, EPA would not consider the notice complete and the review period would not begin.

Under the mandatory contact options (Options 1, 2, and 3), the importer will incur out-of-pocket expenses to contact foreign suppliers and manufacturers. Submitters under Option 4 may also incur these out-of-pocket expenses if they believe that foreign suppliers or manufacturers have information necessary for their notices, but they will not be required to do so. Under all four options, if submitters do not include enough information for an adequate review, EPA may require more information under its proposed supplemental reporting authority, or it may prohibit or limit the import of the substance under section 5(e) pending the submission of additional data. These actions are most likely to occur under Option 4, which does not require that the importer contact foreign suppliers or manufacturers; they are least likely with Options 1 and 2.

Foreign manufacturers and suppliers will incur costs if they submit information under any of the options. Of the mandatory-contact options, Option 1 will be the most costly, Option 3 the least. The Foreign Manufacturers/Suppliers Forms in Option 1 and

2 will be less extensive than the domestic forms proposed on January 10, 1979, and October 16, 1979, respectively; the costs of filling them out will be correspondingly less. Under all these options, submissions by foreign manufacturers and suppliers are voluntary.

Foreign manufacturers and suppliers would incur a nonmonetary cost because of the risk of trade secret disclosure. This risk would decrease from Option 1 to Option 4, because the amount of information submitted to EPA would probably decrease. In each option, there may be a conflict between EPA's and the U.S. public's need for information and the foreign manufacturer's desire to protect confidential business information. Because EPA cannot compel foreign manufacturers or suppliers to provide information under TSCA, the deciding factor for this problem is the marketplace -- whether or not the foreign manufacturer or supplier will forego his U.S. market because of a concern for confidentiality.

Benefits to society will depend on how much information EPA receives in the section 5 notice. The more information available to EPA, the more thorough the risk assessment, and the greater the protection of human health and the environment. Since Option 1 and 2 ask for more information than do the other options, they are more likely to benefit society. Under Option 3, EPA would not receive much of the information requested in Options 1 and 2, but it would receive health and environmental effects data and risk assessments, which are likely to be the most useful information. EPA would be least likely to receive data under Option 4.

3. Preferred Option

Foreign manufacturers and suppliers may have information necessary for EPA's review. Under Option 4, the importer is under no obligation to contact these persons, and therefore EPA may not learn of information that would affect its review. For this reason, EPA believes that a mandatory contact provision is necessary and did not propose Option 4.

The major difference in Options 1, 2, and 3 is the amount of information requested from the foreign manufacturer. Option 1 requires the most, Option 3 the least. The forms for foreign manufacturers and suppliers in Options 1 and 2 correspond to the domestic forms proposed on January 10 and October 16. Because EPA now favors a limited form for domestic manufacturers, it believes that the Foreign Manufacturers/Suppliers Form should not exceed the October 16 requirements. It prefers Option 2, which would require the submitter to ask foreign manufacturers and suppliers to complete a limited form consistent with the October 16 reproposed form. However, the Agency solicits comments on whether Option 3, which requires submitters to ask foreign manufacturers and suppliers only for health and safety data and risk assessments, would meet its needs.

G. Exporters

Section 12(a) of TSCA provides that the Act applies to chemical substances manufactured solely for export if EPA finds that they will present an unreasonable risk to health or the environment within the United States. Therefore, if the manufacture or processing of a new chemical substance presents such a risk -- for example, as a result of worker exposure or release to the environment -- EPA would be authorized to control it, preferably before the risk occurred. In the proposed rulemaking, EPA has considered three alternative approaches to premanufacture notification for new chemical substances manufactured solely for export: exporter notification under section 5, exporter reporting under section 8(a), and no exporter reporting.

1. Major Options

Option 1 -- Exporter Notification under Section 5(a)

Under this option, proposed on January 10 and October 16, EPA would require section 5 notices from manufacturers producing new chemical substances solely for export. Submitters would not provide information on uses and exposures occurring outside the United States. They would complete the exporter form proposed on October 16.

Option 2 -- Exporter Reporting under Section 8(a)

This option would require exporters to submit a report under section 8(a) containing the same information required in the Option 1 exporter notice. The notice would be filed 90 days before first manufacture. Companies with annual sales of less than $1 million would be exempt.

Option 3 -- No Exporter Notification

Persons would not be required to report the manufacture of new chemical substances solely for export.

2. Discussion

Options 1 and 2 require that manufacturers of new chemical substances intended solely for export notify EPA 90 days before they begin manufacture. In Option 1, the submission would be under section 5, in Option 2 under section 8. In both cases, EPA would learn that a person intended to manufacture a new substance for export before that manufacture took place. The notices would be similar in their information requirements; they would ask for the information the October 16 reproposal required of manufacturers producing a substance for the domestic market, except that they would not request information on uses and exposure occurring outside the United States. Under both options, EPA would have 90 days to assess the risk and determine the hazard, if any, posed by the new substance before manufacture began. The similarity between Options 1 and 2 ends here.

Under Option 1, if EPA finds that an export-only chemical poses an unreasonable risk within the United States, it can act to prohibit or limit its manufacture, processing, distribution in commerce, or disposal under section 5(f). If EPA requires additional information for a reasoned evaluation, it can require that information under its proposed section 8(a) letter authority, or it can regulate the substance under section 5(e) pending the development of the information. Under Option 2, EPA would not be able to act based on these authorities, and, if the substance were produced by a small business, which is exempt from report under section 8(a), EPA might not learn of its manufacture. If EPA did receive a section 8(a) notice, it would have to rely on the rulemaking authorities of section 4, 5(a)(2), 6, or 7 to control the substance. In most cases, these rules would require months to promulgate; in the meantime manufacture for export could begin unrestricted. Of course, if a person intended to manufacture the substance for a domestic use, he would have to submit a premanufacture notice.

The costs of preparing and submitting notices under Options 1 and 2 are similar. According to ICF estimates, costs of submitting a section 5 export notice will range from $1,200 to $6,900, somewhat less than the cost to complete a domestic notice form (Economic Impact Analysis, p. 167). EPA believes that costs of preparing a notice under section 8(a) will fall within the same range because the report will contain essentially the same information.

It is difficult to estimate the market size of chemicals made solely for export, but EPA believes that it is relatively small. According to the Economic Impact Analysis (p. 167), solely-for-export chemicals probably do not represent a large proportion of total business for most firms. Therefore, EPA believes that the impact of exporter notification would be slight. Exporters will generally have somewhat less of a reporting burden than do other manufacturers subject to premanufacture notification.

EPA costs to review submissions and to protect confidential business information are also similar under Options 1 and 2. A difference in cost would occur however, if EPA needed more information, and the manufacturer did not submit it voluntarily. Under Option 1, EPA could make a letter request under section 8(a) or, in some cases, issue a section 5(e) order; under Option 2 EPA would have to issue a separate 8(a) reporting rule or a section 4 testing rule. These would require considerably more Agency time and resources; they would involve individual rulemakings instead of the expedited procedures possible under Option 1.

Option 2 will narrow the universe of export-only manufacturers who will be subject to premanufacture notification because section 8(a) has a small business exclusion. Manufacturers with annual sales under $1 million will not be required to report. This reduces the coverage under Option 2, but it also lowers the overall costs for industry and EPA.

Under Option 3, manufacturers do not incur the cost of reporting export-only new chemical substance to EPA. EPA, likewise, will not have to review notices on these exports. From EPA's and society's viewpoint, however, Option 3 is the most costly. EPA will have no way to learn of plans to manufacture a new chemical substance solely for export and will not have an opportunity to evaluate the substance for any risks associated with its manufacture in the United States. If such manufacture does involve a hazard -- for example, to workers during manufacture or to the environment as a result of waste disposal -- EPA will learn of it only when damage occurs. The Agency, therefore, may have difficulty in acting quickly to stop or prevent damage to health and the environment. Society will incur costs associated with the hazard, and will suffer damage that might have been prevented if EPA had been notified before manufacture began.

3. Preferred Option

EPA prefers Option 1, which combines the exporter notification requirements proposed on January 10 and the exporter form proposed on October 16. The Agency believes that it is essential to take every possible step available under section 5 to prevent hazards associated with new chemical substances. Commenters on the January 10 and October 16 proposal argued that section 12(a) of TSCA prohibits EPA from requiring section 5 notices for new chemical substances manufactured solely for export. Section 12(a)(1) states that, except for section 8, TSCA does not apply to a substance that is manufactured solely for export. This general principle, however, is qualified by section

12(a)(2), which provides that the Act applies to such a substance if EPA finds that it will present an unreasonable risk to health or the environment within the United States. If EPA is not aware that a new substance is being manufacturing domestically, the Agency could not act to regulate the substance until a significant health or environmental problem occurred. This is contrary to the preventive approach to toxic substances embodied in section 5. Therefore, when read in light of the entire framework of TSCA, section 12 authorizes EPA to require premanufacture notices for new chemical substances manufactured solely for export.

The notice requirements for Options 1 and 2 are very similar. However, the Option 2 approach does not allow EPA the same opportunity to act on exported substances before manufacture begins. Option 2 exporters can begin to manufacture substances that EPA determines to be hazardous while EPA assembles the necessary data to undertake a regulatory action. Under Option 1, EPA will be able to act effectively in cases of unreasonable risk before any harm has occurred.

H. Supplemental Reporting

For certain chemicals of concern, EPA may need additional information from notice submitters or other persons during the review period. This is likely if EPA adopts the limited reporting requirements of the October 16 reproposal. In many cases, submitters will provide the information voluntarily. In others, however, they may not cooperate. In these cases, EPA needs a way to obtain the information quickly, before it is too late to act under section 5(e) or 5(f). EPA may also need the authority to gather information from other persons, including processors or persons with health and safety studies.

EPA has considered three approaches to a supplemental reporting authority to provide information for the premanufacture review. Options 1 and 2 require mandatory reporting; Option 3 does not.

1. Options Considered

Option 1 -- January 10 Proposal

Under this option, proposed on January 10, EPA could require certain persons to report additional information on the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance if that information was necessary for an evaluation of the substance, and if it was known to or reasonably ascertainable by those persons. The notice submitter, potential processors of the new chemical substance, and manufacturers or importers of reactants of unknown identity or composition used in the manufacture of the new chemical substance could be subject to the requirement. The Assistant Administrator for Pesticides and Toxic Substances or the Deputy Assistant Administrator for Chemical Control would issue the information requests by letter under the authority of section 8(a) during or after the review period. In addition, EPA could require any person to submit relevant health and safety studies of new chemical substances during or after the review period through a supplemental reporting requirement under section 8(d).

Section 8(a) includes a small business exclusion, which, for the purposes of supplemental reporting, was defined in the January 10 proposal as exempting companies with annual sales of less than $1 million. Therefore, processors of the substance and manufacturers or importers of unknown reactants with less than this sales volume could not be required to report. However, original notice submitters, even if they were small businesses, would be required to provide information that supplemented, provided further detail on, or clarified information in the original notice. EPA believes that small businesses can be required under the authority of section 5 to submit information that could have been required in the original notice. All persons, including small businesses, could be required to submit health and safety studies in their possession under a section 8(d) supplemental reporting requirement, because this section has no small business exclusion.

The criteria for using supplemental reporting in this option are broad. There is no provision to appeal the individual letters requiring information.

Option 2 -- October 16, 1979, Reproposal

Option 2 (the October 16 reproposal), like Option 1, provides a letter-writing authority under sections 8(a) and 8(d) to get additional information necessary for Agency review of a new chemical substance. It applies to the same persons, but differs from Option 1 in several respects. Under Option 2, criteria governing EPA's use of supplemental reporting are more detailed. Option 2 also specifies the types of information EPA may require if these criteria are met. In addition, if original notice submitters are small businesses, they need only supply information that explains or clarifies the premanufacture notice, not information that supplements it. The reporting requirement applies only during the review period; it does not extend beyond the close of the period, as it does in Option 1. Option 2 also provides a mechanism that allows submitters to appeal individual requirements to supply information.

Option 3 -- No Mandatory Supplemental Reporting

Option 3 does not provide for mandatory supplemental reporting. EPA would have to rely on voluntary compliance when it requested more information from submitters and other persons. If they did not respond, EPA would have to issue a separate section 8 rule to get the information. Or, if a substance met the appropriate criteria, EPA could issue a section 5(e) order prohibiting or limiting the manufacture, processing, distribution in commerce, use, or disposal of the substance pending the submission of the necessary information.

2. Discussion

The adoption of a limited notice form (see Section II(A), Reporting Requirements) provides a persuasive argument for Options 1 and 2. A comprehensive form, such as the one proposed on January 10, 1979, generally gives information sufficient for a detailed evaluation of a new chemical substance, if that information is known to or reasonably ascertainable by the submitter. Because only some new chemicals will undergo detailed review, this comprehensive form may impose an unnecessary burden on many notice submitters. The limited form of the October reproposal reduces the initial burden of notice submission. With the limited form, however, EPA needs a way to obtain more information on chemicals of concern. Supplemental reporting provides this. When EPA requires more information to determine if a new chemical substance is a potential candidate for regulatory action, it can request this information under its proposed supplemental reporting authority.

Option 3, which has no mandatory supplemental reporting requirement, will provide difficulties for EPA's review if a limited form is adopted. EPA can request the information, but it does not have the authority to enforce its request, as it does under Options 1 and 2. Under this option, the Agency must rely on industry cooperation.

Many commenters on the January 10 proposal (Option 1) questioned EPA's authority to require information by letter. They argued that rulemaking on a case-by-case basis was more consistent with the Act. The case-by-case approach is proposed as Option 3. Under this option, EPA would promulgate a separate section 8(a) or 8(d) reporting rule each time the Agency needed more information. The problem with this approach is that the 4 to 6 months required for each rulemaking would conflict with the 90-day (or at most 180-day) review period for new chemical substances. The time needed to promulgate an individual rule for a specific chemical, together with the time before EPA received data under the rule, would exceed the statutory review schedule. This approach would limit the usefulness of the information received, and it would generally foreclose regulatory action based on that information under section 5(e) or 5(f) -- actions that must be taken within 135 days of receipt of a section 5 notice.

For this reason, EPA believes that a section 8 letter-writing authority provides a better approach. In January and October in a rulemaking subject to notice and comment, EPA proposed and reproposed procedures for using the authority, the criteria for when it would be used, the kinds of information that could be required under it, and the procedures for appeal of individual requests for information. With this general framework in place, EPA could secure necessary information during the review period in an expedited fashion. The ready availability of information, or the possibility of determining that it is lacking, is particularly important for actions under sections 5(e) and 5(f).

Under Options 1 and 2, EPA would informally request information from the submitter or other persons before it sent a section 8 reporting letter. If the information was provided, EPA would avoid further administrative costs, and the recipient of the request would incur only the costs of preparing and sending the information. Costs for submitters who failed to respond to the informal request but did respond to the section 8(a) letter would be no higher, unless EPA as a result of the delay extended the review period under section 5(c). Failure to respond to the section 8(a) letter might lead to an enforcement action or regulation of the new chemical substance under section 5(e) or 5(f). In this situation, the cost to EPA and the submitter, of course, would be higher.

It is difficult to estimate the out-of-pocket costs of responding to a section 8 supplemental reporting requirement. The cost will be determined by the frequency with which EPA uses that authority. This in turn will be affected by the level of detail in the original submissions. The costs of the specific responses will vary with the chemical, the person subject to the reporting requirement, and the information requested.

Costs will be different in Options 1 and 2. Option 1 is broader, both with respect to the situations it covers and the information that can be requested. Therefore, out-of-pocket costs should be higher for Option 1. The appeal procedure of Option 2, however, will entail an additional cost. An appeal will involve administrative costs for EPA (diverting resources from the review of other substances) and for the appealing party. Nevertheless, commenters on the January 10 proposal argued that an appeal procedure was necessary to provide the submitter protection from arbitrary action by EPA.

Costs to industry other than out-of-pocket costs are more difficult to measure. The introduction of new substances into the market may be delayed if EPA extends the review period under section 5(c) to allow for supplemental reporting. However, the effect of this should not be great, because the substances subject to supplemental reporting will be slated for detailed review. In this case, the notice period would have been extended even without the supplemental reporting requirement.

The effect of Option 3 on industry is also difficult to assess. On the one hand, submitters will not be subject to reporting under the section 8 letter-writing authority. However, if they do not provide sufficient information in their notices, and they do not later provide the information voluntarily, EPA may be required to take more actions under sections 8 and 5(e). This situation could be particularly detrimental to the submitter if the information requested by EPA would have decreased the Agency's concerns and eliminated the need for regulatory action.

To protect human health and the environment from risks associated with new chemical substances, EPA must be able to secure information on these substances and to act under section 5 before they have entered commercial production. Under Option 3, which has no mandatory supplemental reporting authority, EPA would often find it difficult to act on new substances during the review period. In many cases, it would lack the necessary information to support an action under sections 5(e) or 5(f). Individual, case-specific rulemakings under section 8 to secure the necessary information would rarely provide that information before the review period -- and the possibility of acting under section 5(e) or 5(f) -- had ended. Options 1 and 2, however, ensure that EPA has the authority to get necessary information during the review period.

3. Preferred Option

EPA did not propose Option 3, because a no-mandatory-reporting scheme would limit its ability to fulfill the mandate of section 5. EPA has no assurance that information will always be given voluntarily. When it is not, the Agency will find it extremely difficult to assess the risks of a new chemical substance and to act on potentially hazardous new chemicals before they cause harm to human health or the environment. Furthermore, a supplemental reporting authority will eliminate the need for a more extensive and burdensome section 5 notice form. Without section 8 letter-writing authority, EPA will lack a way to obtain more information on an expedited basis, and a major justification for the streamlined form will be removed.

Of the two options discussed, EPA prefers Option 2. Although Options 1 and 2 are very similar, EPA believes that Option 2 addresses some of the chief concerns expressed in the comments on the January 10 proposal, while still meeting the information needs of the Agency and the public. The January and October proposals have provided adequate opportunity for notice and comment by persons potentially subject to supplemental reporting under Option 2. This option also includes an appeal procedure, which provides individual redress for persons subject to supplemental reporting. Option 2 further restricts the scope of supplemental reporting by limiting it to the notice review period, by setting forth in more detail the criteria governing EPA's use of supplemental reporting, and by specifying the types of information EPA can request. These changes clarify the scope of EPA's authority for industry, and they establish specific guidelines for the Agency.

I. Processor Notification

Manufacturers of several classes of chemicals are specifically exempt from the Inventory and from section 5 requirements: byproducts; tobacco and tobacco products; nuclear materials; substances used solely as pesticides, firearms, ammunition, foods, food additives, drugs, and cosmetics; and substances manufactured before January 1, 1975, and not processed or reported for the Inventory. In addition, persons manufacturing new chemical substances under test marketing exemptions, and persons manufacturing new substances in small quantities solely for research and development (R&D), are exempt from notice requirements if they comply with EPA restrictions for these activities. The substances described above are referred to as "exempt substances" in this section.

A processor notification requirement for all exempt substances would close a gap in the section 5 regulatory scheme by requiring persons to submit notices to EPA if they intended to process any exempt substance for nonexempt purposes. Without such a requirement, a new substance manufactured or imported for an exempt purpose (such as a pesticide) could be processed in any quantity for a TSCA use without a report being submitted to EPA and without prior EPA review for possible effects on health or the environment.

EPA has considered several alternative approaches to resolving this issue. The approaches differ by who must report, what activities trigger reporting, what information must be reported, and what TSCA authorities they depend on. This section considers four major options; other options are discussed in the Economic Impact Analysis (Part II, Chapter 8) and the August 15, 1980, proposed processor notification rule (45 FR 54645).

1. Options Considered

Option 1 -- January 10 Proposal

This option, proposed on January 10, 1979, would require manufacturers or importers to report the processing, use, or distribution of certain exempt substances. Specifically, a manufacturer or importer would have to submit a section 5 notice 90 days before he processed, used, or distributed an R&D or test-marketed chemical in a manner inconsistent with the terms of the exemption. Persons who did not manufacture or import an exempt substance, but who intended to process the substance for a TSCA commercial purpose, would not be permitted to submit a notice. Substances reported under this option would be added to the Inventory when commercial activity began. Mandatory notification costs under the January 10 proposal are estimated to range from $3,740 to $22,160 (ADL, Impact of TSCA Proposed Premanufacturing Notification Requirements, p. V-17).

Option 2 -- August 1980 Proposed Processor Reporting

Under this option, proposed by EPA on August 15, 1980 (45 FR 54642), persons would be required to submit section 5 notices at least 90 days before they processed a previously exempt substance, as defined above, for a TSCA commercial purpose. Processor notification would be required whether or not the person was also the original manufacturer or importer. The notice would include all the information required by the notice form proposed on October 16, 1979, as well as the name of the supplier or future suppliers of the substance. The cost of providing mandatory information under this alternative would range from $1,155 to $8,925 (ICF, Economic Impact Analysis, p. 186).

EPA would require notices under the authority of sections 5(a)(1) and 5(a)(2). After the review period, if EPA did not take action on the substance, the submitter could process it for TSCA commercial purposes, and it would be added to the TSCA Inventory.

Option 3 -- Section 8 Processor Notification

All persons who process previously exempt substances for TSCA commercial purposes would be required to report to EPA under section 8(a) at commencement of processing. Section 8(a) notices would provide company name, contact person, chemical identity, amount of the substance to be processed, an estimate of consumer and worker exposure, a description of categories of use, available health and safety data, and the name of the supplier. The cost of providing this information would range from $724 to $4,450 (ICF, Economic Impact Analysis, p. 186).

"Small processors" are exempt from section 8(a) reporting and would not submit notices under this alternative. Substances reported to EPA would not be added to the TSCA Inventory when processing began.

Option 4 -- August Proposal with Exemption for One-time Processing

Option 4 would require processor reporting for exempt substances under section 5, as outlined in Option 2. However, the reporting requirement would be coupled with an exemption scheme permitting the limited processing of selected chemicals.

The exemption scheme would apply to R&D and test-marketed substances processed on a one-time basis for TSCA commercial purposes solely as an alternative to disposal. Persons who intended to process R&D and test-marketed substances once as an alternative to disposal in quantities under 500 pounds would not be required to report. Persons who intended to process such substances once as an alternative to disposal in quantities over 500 pounds would be subject to limited reporting requirements under section 8. These requirements would be the same as the requirements outlined for Option 3. Substances reported under section 8 would not be added to the Inventory when processing began, and small businesses would be exempt from this reporting.

2. Discussion

In considering the problem of processing previously exempt substances for TSCA commercial purposes, EPA addressed several issues. These include: (1) Whether to require notification for such processing, (2) What the applicability of the reporting requirement should be, (3) If reporting was required, what data would have to be submitted, (4) How EPA could regulate chemicals of concern under TSCA authorities after the notices were received, (5) Whether to add reported substances to the TSCA Inventory, and (6) What costs would be imposed on industry and EPA. Resolution of each of these issues played a part in shaping the approach EPA proposed. These are discussed in turn.

a. Notification for commercial processing of exempt substances. If previously exempt chemicals are processed for commercial purposes, but the processors are not permitted to submit a notice, EPA will be unable to assess the risks associated with that processing, or with distribution in commerce, use, or disposal of the substance for TSCA commercial purposes, before those activities occur. Yet these activities might pose significant risk to health or the environment. Therefore, EPA proposes to require reporting for commercial processing of exempt substances. This reporting is consistent with section 5 of TSCA, which requires the Agency to review new chemical substances and significant new uses before manufacture or import for commercial purposes. Many substances are exempt from Inventory and section 5 reporting when they are manufactured or imported, yet persons other than the manufacturer or importer might process them for TSCA commercial purposes. By requiring reporting before these substances are processed for TSCA purposes, EPA will be able to review any risks they will pose, in the same way that the Agency considers risks associated with new chemicals to be manufactured or imported for TSCA purposes.

b. Authority for and scope of processor notification. Under the January 10 proposal (Option 1), EPA requires section 5 notification by manufacturers and importers of R&D and test-marketed substances before they process, distribute, or use those substances in a way inconsistent with the terms of the exemption. Other persons could process exempt substances for TSCA commercial purposes without notification. EPA, however, believes that requiring reporting for only some classes of exempt substances is not desirable because any exempt substance could be processed for a TSCA purpose and placed in commerce. Singling out only R&D or test-marketed substances for reporting does not fulfill EPA's goal of reviewing substances never reported under TSCA before they are processed for TSCA commercial purposes. Because the January 10 proposal (Option 1) would only require reporting for R&D and test-marketed substances, and then only if the processor of the substance was the manufacturer or importer, EPA decided that this approach does not sufficiently cover all substances of concern. The Agency prefers an option that requires notification for all categories of substances.

EPA could issue such a rule under section 8(a) (Option 3) or sections 5(a)(1) and 5(a)(2) (Option 2). Under Option 3, EPA would require all processors of previously exempt substances for TSCA commercial purposes to submit limited section 8(a) notices at the commencement of processing. Small processors would be exempt from reporting because section 8(a) contains a small business exemption. Under Option 2, proposed on August 15, 1980, EPA would require that processors, including small processors, submit a section 5 significant new use notice at least 90 days before processing began. EPA has assessed the factors listed in section 5(a)(2), and, based on this assessment, the Agency proposed in August that the transition of chemicals from exempt manufacture or import to nonexempt commercial processing constituted a "significant new use" under TSCA. Therefore, under Option 2, persons intending to process a previously exempt substance for TSCA commercial purposes would be required to submit a notice under section 5(a)(1)(B).

Options 2 and 3 make all categories of exempt substances subject to reporting, if they were processed for TSCA commercial purposes. EPA, however, is considering an exemption for one category of processing. Option 4 would permit processing with no notification for R&D or test-marketed substances processed in lieu of disposal for nonexempt purposes in quantities of less than 500 pounds. Persons processing substances under the same circumstances in quantities of greater than 500 pounds would submit section 8 notices, but the substance would not be added to the Inventory. This distinction by production volume exempts processing likely to present less of a risk, because less of the substance would be processed. This scheme would mean that a person would not have to dispose of a chemical that had only a limited one-time commercial application if section 5 notification costs were higher than the expected financial return for the commercial application.

EPA believes that substances manufactured solely in small quantities for R&D or for test marketing may belong in a separate category from other exempt substances. For example, a substance manufactured as a pesticide, food, or drug may fail in a nonexempt commercial use, but will still have its primary use as a pesticide, food, or drug as an alternative. However, a substance manufactured or imported for R&D or for test marketing may only have a nonexempt commercial use as an alternative to disposal. In this case, processing on a one-time or limited basis to "use up" the substance is much more likely to occur.

Several arguments can be made for allowing this processing without EPA notification. First, use of the substance may cause less harm to the environment than disposal. Second, if notification costs are greater than the benefits of one-time processing, the processor may incur an increase in overall costs. Third, it may not be desirable to add a substance to the Inventory if it will immediately lose its commercial status. If other TSCA uses are later discovered, it may be more appropriate for EPA to review the substance at that time, when more information is available. However, there is a strong argument for mandatory EPA notification. The "using up" of the substance may involve significant exposure to humans and the environment.

EPA does not now have sufficient information on the situations in which persons process R&D and test-marketed chemicals for commercial purposes on a one-time basis as an alternative to disposal. Therefore, it has not proposed this exemption, but invites further comment.

c. Information requirements. Under Option 1, EPA would require that submitters complete the notice form proposed on January 10, 1979 -- although notification would be required only for manufacturers or importers processing an R&D or test-marketed substance in ways inconsistent with the terms of the exemption. In the August 1980 proposal, EPA reduced the information requirements to those of the October 1979 form. Section II(A), Reporting Requirements, of this Regulatory Analysis explains this in detail. In the August proposal, however, EPA also added a few data requirements for processors. These data were the names of suppliers and future suppliers; descriptions of the manufacturing processes, if known; and, for R&D substances, any information on health or environmental risks that the submitter received under section 720.14(a)(2) or evaluated under section 720.14(c) of the January proposal. These additional requirements are not burdensome and will assist the Agency in assessing the risks associated with the commercial processing of exempt substances.

Under Option 3, which requires a limited section 8(a) notice, EPA would reduce the reporting burden for submitters still further. EPA, however, does not believe that such a limited notice would provide enough information for an initial assessment of the risks posed by a chemical.

d. Control of reported chemicals. If EPA decides to regulate exempt substances reported under any of the various options, it is important that these requirements be imposed expeditiously to protect the public and the environment before any possible harm occurs. The options would require EPA to use different authorities to control chemicals of concern, depending on whether the chemical was initially reported under section 5 or section 8. As discussed more fully in Section II(G) of this Regulatory Analysis, regulation under section 5 would be less burdensome to EPA, and it would allow more timely action.

Under the section 5 notice options, EPA would use sections 5(e) and 5(f) to regulate chemicals that may or will present unreasonable risks. These sections allow EPA to act by order, with court action as necessary. Substances reported under section 8 would not be subject to regulation under section 5(e) or 5(f). Instead, the Agency would be forced to act on chemicals under section 4, 5(a)(2), 6, or 7, which would entail greater burden and, in most cases, would require considerable time to promulgate.

e. Addition of reported substances to the TSCA Inventory. Under Options 3 and 4, EPA would not add previously exempt substances to the TSCA Inventory when it received a section 8 notice. Section 8 notices, as described earlier, might not contain information necessary for an initial screen, even though it was known or reasonably ascertainable. Therefore, these notices may not provide enough information for the evaluations that EPA wishes to conduct on exempt substances before they are processed for nonexempt commercial purposes. For this reason, these substances should not be placed on the Inventory. If the substances were placed on the Inventory, persons who intended to manufacture or import them for TSCA commercial purposes would not notify EPA; as a result, the substances might enter commercial production without review under section 5. Under Option 2, the substances would be subject to section 5 notice before they were manufactured or imported for TSCA commercial purposes, and would go into production for these purposes only after EPA had evaluated a full section 5 notice.

f. Reporting costs for industry. The initial costs of submitting mandatory information under the Options 1, 2, and 3 are given in Table II-4.

TABLE II-4

ESTIMATED COSTS OF COMPLETING MANDATORY PROCESSOR FORM

Option	Cost
Section 8(a) reporting (Option 2)	725- 4,450
August 15, 1980 (Option 3)	1,155- 8,925
January 10, 1979 (Option 1)	3,740-22,160

Section 8 notices would be significantly less expensive for submitters than section 5 notices. Section 8 notices would also impose lower postsubmission costs. Because notices would be submitted at commencement of processing, there would be no delay. However, section 5 notices would have to be submitted later if a person intended to manufacture or import the substance for TSCA commercial purposes. If both section 8 and section 5 notices were submitted, the cost and burden to industry would be higher than the costs of submitting either notice alone.

Under Option 2 (August reproposal), EPA would obtain enough information to conduct an initial assessment; if necessary, it could then require more data on chemicals of concern through supplemental reporting. Therefore, the August proposal reduces the cost of section 5 notification without substantially reducing the effectiveness of EPA's review.

The January 10 approach (Option 1) and section 8(a) processor notice (Option 3) would involve a cost to industry not reflected in the costs of notification. Under the January 10 approach, only processors of R&D and test-marketed substances would be permitted to submit section 5 notices; other exempt substances processed for TSCA commercial purposes would not be reported and would not go on the Inventory. Under Option 3, processors would submit section 8 notices, but the previously exempt substances would not be added to the Inventory. In both Options 1 and 3, therefore, persons would have to submit a section 5 notice before they could manufacture or import previously exempt substances that had been processed for TSCA commercial purposes. If the processor was not the manufacturer or importer, and the manufacturer learned of the commercial processing, the manufacturer would be required to halt distribution for the commercial purpose and submit a notice.

Under Option 2, however, the reported substances would go on the Inventory. Processors and any other persons could then manufacture or import the substance for nonexempt purposes without the potential delay of notification. They would also be able to avoid interruptions in supply that would occur in Options 1 and 3 if the manufacturer learned of the processing but did not submit a notice.

3. Preferred Option

EPA prefers Option 2, which it proposed in August 1980. Processor reporting as proposed offers the most effective environmental protection because it allows EPA to review exempt chemicals before they are processed for TSCA purposes. To assess the risks that might be posed by these chemicals, the Agency must require enough information to conduct an initial screen. Option 2 achieves this by requiring that processors supply the information requested on the October 16 form, if it is known to or reasonably ascertainable by the submitter. Also, because processors would submit section 5 notices under Option 2, EPA will be able to regulate previously exempt substances processed for TSCA commercial purposes under sections 5(e) and 5(f). The substances would be added to the TSCA Inventory when they are processed for commercial purposes. Finally, under this option, small as well as large processors would report.

J. Possession or Control

Under section 5(d)(1)(B), a notice submitter is required to provide any test data in his "possession or control." In the January 10, 1979, proposal, EPA defined information in a submitter's possession or control as information: (1) In the submitter's own files, (2) In commercially available data bases to which he has purchased access, or (3) In files maintained in the course of employment by employees or other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the substances. This definition is common to the four options discussed in this section. The options, however, differ in their treatment of test data in the possession or control of companies affiliated with the submitter, and in the participation of these affiliated companies in the commercial development of the new chemical substance.

1. Options Considered

Option 1 -- In Possession of Subsidiaries, Parent Company, and Parent's Subsidiaries Associated in the Present Venture

The first option was proposed on January 10, 1979. Under this option, "possession or control" means in the possession or control of the submitter, any of his subsidiaries, his parent company, or any company that the parent company owns or controls if the subsidiary, parent company, or subsidiary of the parent company is associated with the submitter in the research, development, test marketing, or commercial marketing of the substance. Under this option, one company "owns or controls" another company if it owns or otherwise controls at least 50 percent of the other company's voting stock.

Option 2 -- In Possession of Subsidiaries Associated in the Present Venture

The second option includes data in the possession or control of the submitter or any of his subsidiaries if they are associated with the submitter in the research, development, or marketing of the new chemical substance. Unlike Option 1, however, it does not include data possessed or controlled by a parent company or by companies owned by a parent company, even if the parent company or its subsidiaries are associated with the submitter in the research, development, or marketing of the substance.

Option 3 -- In Possession of Subsidiaries, Parent Company, and Parent's Subsidiaries, Including Those Not Associated in the Present Venture

Like the first option, Option 3 defines possession or control to mean in the possession or control of the submitter, any of his subsidiaries, his parent company, or any companies owned or controlled by the parent company. Again, owning or controlling is defined as owning or controlling at least 50 percent of a company's voting stock. However, Option 3 does not limit the definition to companies associated with the submitter in any particular venture.

Option 4 -- Modified Option 1

The fourth option has been considered by EPA, but is not analyzed in the Economic Impact Analysis. Like Option 1, this definition includes data possessed or controlled by the submitter, any of his subsidiaries, his parent company, or any company that the submitter or his parent company owns or controls, if the subsidiary, parent company, or subsidiary of the parent company is associated with the submitter in the research, development, test marketing, or commercial marketing of the substance. Under this option, unlike Option 1, one company "owns or controls" another company if the parent company exercises "control in fact" over the other company, irrespective of its percentage of stock ownership in that company. Control in fact would mean the direct or indirect possession of the power to direct the management and policies of a company, whether through ownership of voting securities, by contract, or otherwise.

2. Discussion

Under each option, submitters possess or control data in commercially available data bases to which they have purchased access. The cost of retrieving data from such a data base is reasonable, and the data may be valuable to EPA. Also under each option, submitters possess or control information in the files of their employees and agents. This is necessary to secure relevant data and should not be unduly burdensome to submitters.

Options 1, 3, and 4 require the submission of data possessed by subsidiaries, parent companies, and subsidiaries of parent companies in addition to data possessed by the submitter. This requirement is designed to obtain sufficient data without being unduly burdensome. Without this comprehensive approach, many data might be missed since chemical research and testing may be performed by parent corporations and their subsidiaries. In addition, if the definition did not include parent's subsidiaries, companies could reduce reporting requirements by effecting a corporate change from divisions to wholly owned subsidiaries. Because research may be performed by the foreign affiliates of submitters, the definitions would also apply to those companies.

Option 2 is limited to the submitter and its subsidiaries. This definition is less burdensome than Option 1. However, it would not reach relevant data gained through research or testing by parent companies and their subsidiaries if that data were not contained in the files of the submitter.

In Options 1, 2, and 3, one company is considered to own or control another if the parent company owns or controls the majority of voting stock of the other company. In Option 4, one company is considered to own or control another if the parent company exercises control in fact over the other company irrespective of its percentage of stock ownership in that company. This definition would reach data not reached by the other options. It follows the approach of other statutes and regulations, such as the Securities and Exchange Act and the regulations implementing the Export Administration Act. The definition could be interpreted on a case-by-case basis, using rebuttable presumptions of control based on objective criteria. However, because it is not a purely objective standard, this option would be harder to administer than the other options.

Options 1, 2, and 4 limit their reach to companies associated with the submitter in some aspect of a particular venture. Option 3 is not limited to companies associated with the submitter in any particular venture. Theoretically this definition would yield the most data. However, the files of companies not working on a venture involving the substance in question may contain data of marginal relevance. Further, the definition may create burdensome search requirements since, in some cases, it would reach hundreds of companies.

3. Preferred Option

EPA prefers the definition in Option 1, which was proposed on January 10, 1979. While the definition extends the reporting requirement beyond the submitter, it is not unduly burdensome. If the companies involved in the venture use an integrated search system, the direct economic impact of the reporting requirements will be minimal.

The preferred definition may not reach data in the possession of companies controlled in fact by the submitter, or data in the possession of companies legally controlled by the submitter but not involved in the development of the chemical substance. These limitations, however, are not of major concern. In practice, companies involved in the development of a chemical substance will assemble the most complete and current data base. In addition, submitters would generally know of data possessed or controlled by a company not involved in the development of the particular chemical substance. Therefore, they would have to describe these data in their notices. EPA could obtain the data through a supplemental reporting requirement under section 8(d) or by a subpoena under section 11(c). To expand the definition beyond that of Option 1 might be unduly burdensome to affected companies. Similarly, any expansion of the concept of corporate control beyond the majority of voting stock ownership standard would be confusing to affected companies and administratively burdensome to EPA.

III. COMPREHENSIVE PROGRAM OPTIONS

The previous chapter discussed various options for resolving each of the ten major issues in the rulemaking. EPA has constructed three basic approaches, or Comprehensive Program Options (CPO's), for section 5 rules by selecting one option from each issue. The CPO's differ in the extent of guidance they give, their scope, and their burden on industry and EPA. Not all the options discussed in the draft Regulatory Analysis or the proposed Economic Impact Analysis are included in the CPO's. This does not mean, however, that they have been eliminated from consideration for the final rules. These CPO's are intended to serve as examples of possible programs. They illustrate the major alternatives that EPA considered in developing proposed section 5 rules, but they do not represent every combination of options that the Agency has considered in the past or is now considering.

The CPO's, which are discussed more fully in Chapter 5 of the proposed Economic Impact Analysis, are summarized in Table III-1. Based on the level of reporting requirements in each of the CPO's, they are referred to in this chapter as:

- CPO 1: Minimum Guidance
- CPO 2: October 16 Reproposal (with processor reporting, as proposed in August 1980)
- CPO 3: January 10 Proposal

CPO 2 reflects the program proposed by EPA. The remainder of this chapter discusses the advantages and disadvantages of each CPO, and explains EPA's choice of CPO 2 as the most appropriate overall program of the three.

1. Options Considered

CPO 1 -- Minimum Guidance

Under CPO 1, EPA offers the least guidance to industry about reporting requirements, and costs of notification to industry -- at least initial costs -- will probably be the lowest. Under this CPO, EPA would not develop a form, but would give minimum guidance to submitters about what information they would have to report. Test data would be defined as in the "possession or control" of the submitter if they were in his possession or control, or in the possession or control of a subsidiary associated with the submitter in the research, development, or

TABLE IV-1

COMPREHENSIVE PROGRAM OPTIONS

Issue	CPO 1	CPO 2	CPO 3
Reporting Requirements	Minimum guidance (Option 2)	Reproposal (Option 3)	Proposal (Option 4)
Confidentiality			
Mechanics	Minimum guidance (Option 3)	Reproposal (Option 2)	Proposal (Option 1)
Timing of substantiation	Section 5(d)(2) notice (Option 2)	Reproposal (Option 3)	Reproposal (Option 3)
Disclosure of chemical identity	Proposal (Option 2)	Proposal (Option 2)	At submission (Option 1)
Incomplete Submissions	Case-by-case (Option 3)	Proposal (Option 1)	Appeals (Option 2)
Customer Contact	No mandatory contact (Option 4)	Unknown Uses (Option 2)	Proposal (Option 1)
Importers	Principal importer (Option 4)	Proposal (Option 3)	Proposal (Option 3)
Foreign Manufacturers	Health and environmental effects data (Option 3)	Reproposed form (Option 2)	Proposed form (Option 1)
Exporters	Section 8(a) report (Option 2)	Proposal with reproposed form (Option 1)	Proposal (Option 1)
Supplemental Reporting	Case-by-case (Option 3)	Reproposal (Option 2)	Proposal (Option 1)
Processor Reporting	8(a) reporting (Option 2)	August proposal (Option 3)	Proposal (Option 1)
Possession or Control	Submitter's subsidiaries, same venture (Option 2)	Corporate hierarchy, same venture (Option 1)	Corporate hierarchy, any venture (Option 3)

marketing of the substance. Submitters would not be required to contact customers for information. EPA would have no special supplemental reporting authority to gather data not contained in the notice; it could do this only through an individual section 8(a) rulemaking, or in some cases a section 5(e) order. EPA could, however, find that a submission did not meet notice requirements, and the review period would not begin. EPA would make these findings on a case-by-case basis and would not publish formal criteria or procedures.

Of the three CPO's, CPO 1 offers the greatest protection for confidential business information, and in most cases it involves the least cost to the submitter. At the time of submission, the submitters would have to substantiate only claims for information that would appear in the section 5(d)(2) FEDERAL REGISTER notice. They would not develop generic names or descriptions masking confidential information, and no masked information would be published. Confidential chemical identity underlying a health and safety study would be disclosed only after manufacture began.

Finally, CPO 1 is the narrowest of the CPO's in applicability. As under the other CPO's, all domestic manufacturers would report. However, only the "principal importer," not all parties to the import transaction, would be required to submit notices. Principal importers would have to ask foreign suppliers and manufacturers only for health and environmental effects data and risk assessments. Persons manufacturing new chemical substances only for export, and persons who processed previously exempt substances for TSCA commercial purposes, would have to submit a section 8(a) report rather than a section 5(a)(2) notice.

CPO 2 -- October 16 Reproposal

CPO 2 consists of the preferred options discussed in Chapter II of this Regulatory Analysis. It includes the notice form, supplemental reporting requirements, customer-information provisions, and certain aspects of the confidentiality procedures proposed on October 16; it also includes processor notification proposed on August 15 and several options from the January 10 proposal that were not reproposed.

Under CPO 2, submitters would complete the October 16 notice form. They would have to provide test data in the possession or control of their subsidiaries, their parent companies, and their parent companies' subsidiaries, if these companies were involved in the research, development, or marketing of the new chemical substance. There would be no mandatory customer contact, but submitters would have to report the number of committed customers intending to use the new chemical substance in ways not known to them. They would also be required to report the percentage of production volume allocated to these customers during the first three years of production.

CPO 2 includes a section 8 supplemental reporting provision, under which EPA, by letter, could require additional information from the submitter during the review period. The procedures and criteria for this authority would be those proposed on October 16. Also under CPO 2, if a submission had "major deficiencies," EPA could find that it did not meet notice requirements, and the review period would not begin. If the submission had "minor deficiencies," the review clock would stop until the deficiencies were corrected.

The submitter would assert confidentiality claims according to the procedures in the October proposal. He would substantiate all information at the time of submission. Certain categories of confidential information would be masked by generic names and descriptions in public notices; confidential chemical identity underlying a health and safety study would be disclosed only after manufacture began.

The definition of importer would be the same under CPO 2 as under CPO 1, but no specific party to the transaction would be named as responsible for reporting. Instead, all parties would be responsible for seeing that a notice was submitted. The importer would be required to contact foreign suppliers and manufacturers, and ask them to complete a limited Foreign Manufacturers/Suppliers Form. Persons manufacturing a new chemical substance solely for export would submit a section 5 notice. Persons intending to process a previously exempt substance for a TSCA commercial purpose would also be required to submit a section 5 notice.

CPO 3 -- January 10 Proposal

In general, CPO 3 requires the most information, and it is the broadest in scope. Submitters would be required to complete the January 10 notice form. They would have to seek information from all persons who they had reason to believe would purchase the new chemical substance. They would have to provide test data in the possession or control of their subsidiaries, their parent companies, and their parents' subsidiaries, whether or not these companies were involved in the research, development, or marketing of the new chemical substance. During the review period, EPA would have broad supplemental reporting authority, as proposed on January 10. Under CPO 3, EPA would stop the review only if it identified a major deficiency in the submission during the first 30 days of the notice review period. Submitters could appeal an EPA finding that a submission did not meet regulatory requirements.

The submitter would claim confidentiality according to the procedures in the January proposal. As in CPO 2, he would have to substantiate all information at the time of submission; however, the burden would be greater under CPO 3 because in most cases he would have to answer more substantiation questions. Again as in CPO 2, he would be required to provide generic names and descriptions to mask confidential business information in certain categories. Confidential chemical identity underlying a health and safety study would be disclosed at the time of submission.

Under CPO 3, all parties to the import transaction, not just the principal importer, would be responsible for submitting notices. The importer would have to contact foreign suppliers and manufacturers and ask them to complete the detailed form proposed on January 10. Persons manufacturing a new chemical substance solely for export would submit a section 5 notice. Manufacturers and importers intending to process, use, or distribute R&D or test-marketed substances in a manner inconsistent with the terms of the exemption would also submit a notice. EPA would not accept notices from other processors, unless they were also manufacturers of the substance.

2. Discussion

Chapter 5 of the proposed Economic Impact Analysis discusses in detail the relative costs to industry of notification under the three CPO's. The discussion divides costs into presubmission and postsubmission costs. Presubmission costs include out-of-pocket costs and costs of delays; postsubmission costs include out-of-pocket costs, costs of delays, costs of potential trade-secret disclosure, and costs of restrictive action. The following sections of the Regulatory Analysis compare the CPO's on the basis of the assessment of costs to industry in the Economic Impact Analysis, as well as the contractor's and EPA's assessment of costs to the Agency and the public.

a. Reporting and related requirements. CPO 1 imposes the lowest initial reporting burden on industry. Because submitters receive little guidance, they can notify EPA in the manner they consider least costly and most expedient. Furthermore, the amount of information they provide is limited by the absence of a customer-contact provision, by the requirement that foreign manufacturers submit only health and environmental effects data and risks assessments, and by the narrow definition of possession or control.

On the other hand, CPO 1 could involve considerable postsubmission costs for particular submitters. Under a minimum guidance scheme, EPA is likely to receive less information and will have to contact the submitter more often for additional information. This may lead to delay as a result of extension of the review period under section 5(c). Without supplemental reporting, EPA would have to rely on voluntary cooperation, individual section 8(a) rules, or, in some cases, section 5(e) orders. To the extent that EPA acts under section 5(e) because it did not obtain sufficient information in the notice form, or because it had no supplemental reporting procedures, CPO 1 will impose a high postsubmission burden. In addition, the absence of formal, published criteria for determining when a submission does not meet statutory requirements will increase industry uncertainty. Because of this absence, EPA might receive more incomplete submissions than it would under the other CPO's, or submitters might provide EPA more information than the Agency needed for an initial review.

The minimum guidance approach, as discussed earlier, places a heavy administrative burden on EPA. Under the Interim Policy, which offers minimum guidance, EPA has found that in many cases it must organize submitted data. It also expends considerable resources in obtaining data that might have been submitted at little cost initially if appropriate instructions had been provided. Because of the EPA resources spent in these administrative and related functions, fewer resources are available for assessing new chemical substances. As a result, EPA reviews may suffer in the long run.

CPO 2 and 3 provide more detailed guidance to submitters, and they impose broader reporting requirements. The use of forms under these CPO's would considerably ease EPA's administrative burden and reduce industry uncertainty about what information to submit. Standards for section 5 notices would also reduce uncertainty. In general, under CPO 2 EPA would receive information sufficient for an initial screen of new chemical substances; under CPO 3, it would receive information that could support detailed review and possibly regulatory action under section 5(e) or 5(f). Under CPO 2, the submitter would complete the limited October 16 form; under CPO 3, the more detailed January 10 form. EPA would also receive more information under CPO 3 than under CPO 2 because it requires more information from customers and foreign manufacturers, it requires customer contact, and it defines "possession or control" more broadly.

Because CPO 3 requires more information, it will usually involve greater presubmission costs, while CPO 2 is likely to involve greater postsubmission costs. Under CPO 2, EPA will often have less information on hand in the original submission, and therefore the Agency is more likely to seek additional information under the proposed supplemental reporting authority or, in some cases, section 5(e). On the other hand, the scope of the section 8 supplemental authority is more clearly defined in CPO 2 than in CPO 3. For this reason, the costs and uncertainty associated with its use would be less.

CPO 2 and 3, because they allow more efficient use of limited EPA resources and because they provide EPA with information adequate for an initial review, will in the long run lead to more reliable reviews than will CPO 1. In general, the more data EPA has available, the better the review. At the same time, however, the more information EPA receives, the more likely it is that some of the information may be unnecessary for the review. In this case, submitters have borne the cost of providing information of marginal use to EPA. For this reason, EPA prefers the approach of CPO 2 to that of CPO 3. CPO 2 requires less information in the notice by focusing on the information needed for an initial review. In the initial review, EPA can identify and seek more data on substances of high concern. This procedure will ensure a more efficient use of both EPA and industry resources.

b. Confidentiality. CPO 1 involves the lowest initial cost for asserting confidentiality, and it offers the greatest protection for confidential business information. However, it severely limits public participation in the review process. EPA would not publish generic names or descriptions in section 5(d)(2) FEDERAL REGISTER notices, which would restrict public oversight. Under this CPO, delays in obtaining substantiation for other information will also restrict public participation in the review process.

Although the presubmission costs of CPO 1 may be low for the submitter, it will have the highest postsubmission substantiation costs. Under this CPO, the submitter will often have to substantiate information not substantiated when the notice was submitted -- for example, if a Freedom of Information Act (FOIA) request is received. Since the premanufacture review program began, public interest groups have regularly requested premanufacture notices under the Freedom of Information Act. Therefore, under CPO 1, submitters are likely to have to substantiate confidentiality claims weeks or months after the submission of a notice, when they may no longer be as familiar with its contents. Also, because substantiations must be submitted promptly in response to an FOIA request, they will be more burdensome than substantiations at the time of notification.

CPO 2 and 3 will involve greater initial costs for confidentiality claims. Submitters will have to develop generic names and descriptions for certain categories of confidential business information, and they will have to substantiate all claims at the time of submission. The burden of substantiation under CPO 2, however, will be considerably less than under CPO 3, because CPO 2 reduces the number of questions the submitter must answer in substantiating claims for most types of information.

CPO 2 and CPO 3 will entail a greater risk of disclosure of confidential business information because EPA will receive more information. In general, the more information that is submitted, the more information that is subject to disclosure. Also, under CPO 3 confidential chemical identity underlying a health and safety study will be disclosed at the time of submission.

Although CPO 2 and CPO 3 involve higher presubmission costs than CPO 1, their postsubmission costs may be lower. If a Freedom of Information Act request is made for information claimed confidential in a notice, the submitter will have already substantiated his claims. Also, CPO 2 and CPO 3 will allow meaningful public participation, both because generic information will be available to the public and because EPA will review substantiation claims at the time of notification. EPA response to Freedom of Information Act requests will not be delayed by the substantiation process.

c. Applicability. Of the three CPO's, CPO 1 is the narrowest in applicability. All require domestic manufacturers to report. However, under CPO 1, only the "principal importer" need submit a notice; CPO 2 and 3 make all parties to the import transaction responsible for notification. Because several importers will be involved in the submission under CPO 2 and 3, the overall costs of submission under these options are likely to be higher for importers. However, the costs may be shared among the parties, and therefore involve little cost for each. Submission costs for foreign manufacturers and suppliers will be least under CPO 1 because importers of new chemical substances must ask them only to supply health and environmental effects data and risk assessments. Under CPO 2 and 3, importers must ask for considerably more information. Under all the CPO's, however, submissions by foreign manufacturers and suppliers are voluntary.

Under CPO 1, persons manufacturing a new chemical substance solely for export submit a section 8(a) rather than a section 5 notice. Because of the small business exemption in section 8(a), companies with annual sales of below $1 million would not report. Under CPO 2, exporters submit the October 16 form; under CPO 3, they submit the January 10 form. Because the section 8(a) form would require the same information as the October 16 form, presubmission costs of supplying the information would be approximately the same under CPO 1 as under CPO 2 (except for small businesses, who would not report under CPO 1). Other costs associated with CPO 2 -- for example, the broader definition of possession and control -- would make the overall costs of compliance higher. For exporters, presubmission costs of CPO 3 are highest. However, as described in the section on reporting requirements, CPO 3 is likely to involve lower postsubmission costs than CPO 2. CPO 1 will have the lowest postsubmission costs of the three, because EPA will receive section 8(a) notices from exporters and, therefore, will not be able to extend the review period under section 5(c) or act under section 5(e) or 5(f). In this option, EPA could only act under section 4, 5(a)(2), 6, or 7. Because of the burden of these actions, they would be more difficult for EPA to take.

Under CPO 1, processors of previously exempt substances for TSCA commercial purpose would submit a limited 8(a) report. CPO 3 requires manufacturers and importers to notify EPA if they process an R&D or test-marketed substance for purposes inconsistent with the exemption; under CPO 2, all persons who process exempt substances for TSCA commercial purposes must submit a section 5 notice. Because the section 8(a) form requires the least information, submitters under CPO 1 will incur the lowest reporting costs. Submitters under CPO 3 will incur the highest costs because the January 10 form is required, and because the other notification costs associated with this CPO are highest.

3. Preferred CPO

EPA believes that CPO 2 strikes an appropriate balance between the burden it imposes on the chemical industry and the needs of EPA and the public. This program will establish clear notification and review procedures, and it will ensure that EPA receives adequate information for an initial review of new chemical substances. Supplemental reporting will allow EPA, when necessary, to obtain information on substances undergoing detailed review. By concentrating its efforts on substances of high concern, EPA will use its resources most efficiently, without imposing unnecessary reporting burdens on industry. The confidentiality policy will allow the greatest degree of public participation while still protecting confidential business information. In this policy, EPA has provided strong protection for traditional trade secrets, while allowing greater public disclosure of health and safety data -- information important to public participation in the review process.

CPO 1 has the advantage of allowing the submitter maximum flexibility; it generally imposes the least reporting burden; and it involves the least risk of disclosure of confidential business information. EPA, however, did not propose this option for several reasons. CPO 1 involves the highest degree of uncertainty for the chemical industry, particularly because it provides minimum guidance on reporting requirements. In addition, it offers the least protection to the public, not only because its confidentiality procedures will make public participation difficult, but also because EPA will find it difficult to perform adequate reviews within the short time allowed by the Act. The Agency will not receive enough information for the initial review of many new chemical substances, and it will not have procedures adequate for gathering this information during the review period.

CPO 3 will provide EPA with the most information. This is an advantage because, on the whole, the more information EPA has available to it during the review period, the more reliable its reviews will be. In addition, CPO 3 will allow the greatest public participation. This option, however, will also impose the highest overall cost on industry. EPA believes that these costs can be significantly reduced without substantially reducing the effectiveness of the program. The January 10 notice form, the broad definition of possession or control, the customer-contact requirements, and other elements of CPO 3 will in many cases provide EPA with more information than it needs for an initial screen. In CPO 2, the Agency has reduced these burdens, while retaining adequate safeguards. Of the three program options, therefore, CPO 2, the option EPA has proposed, provides the greatest protection for human health and the environment consistent with the needs and concerns of the regulated industry.

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